

# **EXHIBIT 33**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**IN RE JOHNSON & JOHNSON  
TALCUM POWDER PRODUCTS  
MARKETING, SALES PRACTICES, AND  
PRODUCTS LIABILITY LITIGATION**

**MDL NO. 16-2738 (MAS) (RLS)**

***THIS DOCUMENT RELATES TO:  
Converse v. Johnson & Johnson, et al.  
3:18-cv-17586***

**SECOND AMENDED RULE 26 EXPERT REPORT OF  
DANIEL L. CLARKE-PEARSON, MD**

Date: May 28, 2024



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Daniel L. Clarke-Pearson, MD

I am a Professor in the Department of Obstetrics and Gynecology and the Division of Gynecologic Oncology at the University of North Carolina. I am certified by the American Board of Obstetrics and Gynecology as a specialist in obstetrics and gynecology as well as a subspecialist in gynecologic oncology.

## **SUMMARY OF OPINIONS**

I was asked to provide my opinion in response to the following questions:

- (a) Can the use of talcum powder in the genital area cause epithelial ovarian cancer (EOC)? and
- (b) If so, what is the biological mechanism for this occurrence?

It is my opinion, to a reasonable degree of medical and scientific certainty, that the use of talcum powder products, including Johnson's Baby Powder and Shower to Shower, applied to the perineum of women, can cause EOC. My opinion is based on research that I have conducted in the medical and scientific literature as well as my knowledge and experience as an obstetrician-gynecologist and as a subspecialist in gynecologic oncology for over 40 years.

The increased risk associated with the genital use of talcum powder has been consistently described over decades in numerous studies. The mechanism by which talcum powder causes cancer involves: 1) ascension of particles to the fallopian tubes and ovaries; and 2) initiation of a chronic inflammatory process that includes oxidative stress and specific genetic mutations.

My opinion that genital application of talcum powder is a significant risk factor for all users and can cause epithelial ovarian cancer in some women by an accepted mechanism is strongly supported by credible scientific research. When formulating my opinions regarding causality, I considered the extensive body of literature in its totality, weighing the data and information according to its importance using the concepts outlined by Bradford Hill. The Bradford Hill factors include strength of association, consistency, specificity, temporality, biologic gradient, biologic plausibility, coherence, experiment, and analogy. These are discussed in detail later in this report.

## **QUALIFICATIONS**

The focus of my clinical practice, teaching and research for the past 40 years has been the care of women with gynecologic cancers (cancers of the ovary, fallopian tube, uterus, cervix, vagina, and vulva). In addition, I also provide care for complex gynecologic surgical problems (endometriosis, large ovarian tumors, leiomyomata).

I received a BA from Harvard College (major in biology). I spent a year as a laboratory technician developing a device to noninvasively detect deep venous thrombosis. I then attended medical school at Case Western Reserve University School of Medicine (Cleveland, OH). After graduating in 1975, I completed a four-year residency in Obstetrics and Gynecology at Duke University Medical Center (Durham, NC). I then completed a three-year fellowship in Gynecologic Oncology at Duke. From 1982-1985, I was an assistant professor on the Duke faculty (Division of Gynecologic Oncology). From 1985-1987, I was the Director of Gynecology and Gynecologic

Oncology at the University of Illinois (Chicago, IL). I returned to Duke in 1987 to serve as the Director of Gynecologic Oncology and Director of the Gynecologic Oncology Fellowship program. I was appointed a full professor with tenure and was awarded a Distinguished Professorship (James Ingram Professor of Gynecologic Oncology) in 1993.

From 2005 until 2019, I served as Chair of the Department of Obstetrics and Gynecology at the University of North Carolina (Chapel Hill, NC). As the Robert A. Ross Distinguished Professor and Chair, I had administrative responsibilities for over 75 faculty, 28 residents in obstetrics and gynecology and 29 fellows receiving subspecialty training in eight subspecialties. Throughout my career, I provided clinical care to women with gynecologic cancers including surgery, administration of chemotherapy, and conducting clinical trials. Currently, I have a part-time position in the department and continue to educate medical students and residents in Obstetrics and Gynecology and Fellows in Gynecologic Oncology.

I have published over 250 peer-reviewed manuscripts in the medical literature. I have also written over 50 chapters for medical textbooks and edited three medical textbooks. My research has focused on the treatment of gynecologic cancers, surgical techniques, and the prevention of venous thromboembolic (VTE) disease. I have conducted the practice defining clinical trials evaluating various methods to prevent VTE in gynecologic surgery.

I have served on the editorial boards of four peer-review journals (*Obstetrics and Gynecology*, *Journal of Gynecologic Techniques*, *Journal of Gynecologic Surgery* and *Gynecologic Oncology*). I served as a board examiner for the American Board of Obstetrics and Gynecology for eighteen years. I have been actively involved with relevant medical organizations including the American College of Obstetricians and Gynecologists (ACOG), the Society of Gynecologic Oncology (SGO), the American College of Surgeons (ACS) and the Gynecologic Oncology Group (GOG). I have led numerous postgraduate continuing education courses sponsored by ACOG. Most have focused on teaching obstetricians and gynecologists complex pelvic surgery and management (and prevention) of surgical complications. I have served on several ACOG committees (Technical Bulletins, Gynecologic Management and Grievance) and was the chair of the Gynecologic Management Committee that wrote Clinical Opinions distributed to ACOG members. I also served a three-year term on the ACOG Executive Board. As a gynecologic oncologist, I have been an active member of the SGO and have served on a number of SGO Committees and the Executive Board. In 2010, I was the SGO President. As a member of the American College of Surgeons, I have presented CME lectures at the ACS annual meeting and have served on the ACS Obstetrics and Gynecology Advisory Committee and the Commission on Cancer. The GOG is a cooperative group organization sponsored by the National Cancer Institute to conduct clinical trials investigating new treatments to improve the outcomes of women with gynecologic cancers. Many of the publications on my CV (Exhibit A) derive from participation in these clinical trials.

I am a past member of the SGO Ethics Committee, past President of the Council of University Chairs of Ob Gyn (CUCOG), and currently serve as the President-Elect of the Society of Pelvic Surgeons.

My updated *curriculum vitae* is attached as **Exhibit A**.

## **METHODOLOGY AND MATERIALS REVIEWED**

Specifically, in preparing this report, I sought to obtain relevant information through several sources. I primarily relied on a PubMed search of “talc AND Ovarian Cancer”, “Ovarian Cancer AND risk factors”, “Talcum Powder AND Ovarian Cancer”, “Talcum Powder AND Cancer”, “Talc AND Cancer”, “Asbestos AND Ovarian Cancer”, “Asbestos AND Cancer”. These searches provided peer-reviewed papers that included original research, case-controlled studies, cohort studies, meta-analysis studies, and review papers and systematic analysis. I also searched some of the references cited in these papers. Google searches were also performed. I also reviewed a number of textbooks searching for “ovarian cancer risk factors” and “talc/talcum powder”. In addition to the literature derived from these searches, I received relevant materials at my request to clarify a particular topic or answer a question. I approached this research with the same scientific rigor that I would use in my own clinical, academic, and research practice.

I assessed the data and conclusions of these peer-reviewed articles considering the strengths and weaknesses of each particular study. The medical and scientific literature on these topics varies in the quality of the study design and, at times, in conclusions. I approached each article objectively and critically, assessing for factors such as design, power, reputation of author(s), quality of journal, and potential biases. The increased risk associated with the genital use of talcum powder is consistently described over decades.

When formulating my opinions regarding causality, I considered the extensive body of literature in its totality, weighing the data and information according to its importance using the concepts outlined by Bradford Hill. Overall, I believe that the opinions expressed in this report are strongly supported by credible scientific research. The complete list of the materials I considered is attached as **Exhibit B**.

## **BACKGROUND AND OPINIONS**

### **a) Overview of Ovarian Cancer**

Approximately 20,000 women in the US will be diagnosed with ovarian cancer annually. To date, there is no method to screen for ovarian cancer and symptoms associated with ovarian cancer are vague and not specific. Therefore, at the time of initial diagnosis, nearly 75% of women will have ovarian cancer spread throughout the abdominal cavity, lymph nodes and into the lung (pleural effusion). Current treatment includes initial surgery to attempt to remove the bulk of the cancer (“debulking surgery”) followed by treatment with multi-agent chemotherapy. Unfortunately, the majority of women will ultimately die from this malignancy.

Ovarian cancer refers to a group of malignancies found in the ovary. These groups are determined based on the ovarian cells from which they arise – germ cell, stromal, and epithelial cancers. Epithelial ovarian cancers (EOC) involve the cells on the surface of the ovary and can originate in either the ovary or fallopian tube. These account for the vast majority of ovarian cancers (greater than 90%). EOC are further subdivided based on the microscopic characteristics of the cells. These subtypes include serous, endometrioid, clear cell, mucinous, undifferentiated, or mixed. Of these, serous is by far the most common at approximately 70% of EOCs.

### **b) Pathogenesis of Ovarian Cancer**

There are several theories as to the origin of ovarian cancer. One holds that “incessant ovulation” requires “repair” of the ovarian surface epithelium after each ovulation. The “repair” mechanism is prone to generate DNA errors (mutations) that result in malignant transformation. (Fathalla 1971). This theory is supported by observations that events that reduce ovulation are associated with a lower risk of a woman developing ovarian cancer. Pregnancy, breast feeding, and use of oral contraceptives all reduce the risk of ovarian cancer. (Havrilesky et al. 2013; La Vecchia 2017).

Before 2008, it was presumed two other cancers in women (fallopian tube and primary peritoneal) were distinct from ovarian cancer. However, Levanon recognized that many EOCs actually arise in the fallopian tube and metastasize to the ovary and peritoneal cavity. (Levanon, Crum, and Drapkin 2008). This observation is supported by molecular data (especially the frequent finding of P53 mutations in the fallopian tube and EOC metastases). (Fathalla et al. 2013; Kurman and Shih 2016; Dubeau and Drapkin 2013; Chien et al. 2015). Today, we believe that EOC, fallopian tube carcinoma and primary peritoneal carcinoma are the same entity and share similar risk factors and pathogenesis.

By definition, cancer results from gene mutations in normal cells that transform the normal cell into a cell that has lost its regulation of controlled growth. Mutations can occur through a number of processes. Some mutations may be inherited from either the patient’s mother or father. BRCA1, BRCA2 and mismatch repair gene (Lynch Syndrome) mutations are such examples. In most instances, the mutations occur due to exposures such as virus (HPV virus causing cervical, anal, vulvar and oropharyngeal cancers), tobacco smoking (lung cancer) and exposure to x-rays (leukemia). Some exposures result in a chronic inflammatory response that induces mutations as the normal cell attempts to repair damage such as that caused by asbestos (pulmonary mesothelioma, ovarian cancer). These mutations can also occur spontaneously as cells (and individuals) age. (Bottazzi, Riboli, and Mantovani 2018).

### **c) Inflammation and Cancer**

There is a clear link between inflammation (resulting in oxidative stress) and cancer risk. This is true for many types of cancers, including stomach, colon, cervix, mesothelioma, pancreas, and liver, as well as ovary. (Balkwill and Mantovani 2001; Coussens and Werb 2002; Okada 2007; Reuter et al. 2010; Crusz and Balkwill 2015; Fernandes 2015). Inflammation causes cancer through promoting cell proliferation, oxidative stress, DNA damage and gene mutations. This process is associated with many steps in the genesis of cancers including initiation, progression, metastases and chemoresistance.

Both inflammatory cells and cancers produce cytokines and chemokines that contribute to cancer growth and spread. Cytokines, particularly TNF-alpha and IL-1 beta, generate reactive oxygen species (ROS) and reactive nitrogen species (RNS). These are potent mutagens and are comparable to the cell damage caused by ionizing radiation. (Yan et al. 2006). These ROS radicals cause DNA breaks and DNA adducts. The inflammation cascade has been shown to occur in the pathogenesis of EOC. (Shan and Liu 2009; Saed, Diamond, and Fletcher 2017; Khan et al. 2011; Saed et al. 2018; Trabert et al. 2014; Savant et al. 2018; Ding et al. (2021)). Fletcher and Saed exposed normal



ovarian cells and EOC cells to talcum powder and demonstrated significant cellular effects including oxidative stress, cell proliferation, decreased apoptosis, and enzymatic activity corresponding to single nucleotide polymorphisms (SNPs) associated with inflammation and ovarian cancer. (Harper et al. 2019). Recently, Harper and Saed also demonstrated that exposure to Johnson's Baby Powder causes p53 mutations, cell proliferation and malignant transformation in normal ovarian epithelial cells. (Harper et al. 2023).

Talcum powder is known to elicit an inflammatory response in animals and humans. (Eberl and George 1948; Radic et al. 1988; NTP Toxicology and Carcinogenesis Studies of Talc (CAS No. 14807-96-6) (NonAsbestiform) in F344/N.Rats and B6C3F1 Mice (Inhalation Studies) 1993). Shukla demonstrated *in vitro* that crocidolite asbestos and non-fibrous (platy) talc caused expression of genes in ovarian epithelial cells producing inflammatory cytokines. (Shukla et al. 2009). Gates documented absence of some DNA repair mechanisms in patients who were genital talcum powder exposed when compared to controls in the New England Case Control Study. (Gates et al. 2008). In another series of *in vitro* experiments, Buz'Zard transformed normal ovarian epithelial cells to malignant cells by talc exposure. (Buz'Zard and Lau 2007). Akhtar et al. (2010, 2012) also demonstrated oxidative stress in cells exposed to talc particles. Yan and Kahn have demonstrated similar findings in their laboratories. (Yan et al. 2006; Khan et al. 2011). In 2020, Mandarino demonstrated that talc, especially in combination with estradiol, stimulated macrophages to produce increased reactive oxygen species and changes in gene expression that could promote a pro-tumorigenic environment. (Mandarino et al. 2020). In 2021, Emi et al. conducted a follow-up study which found that the "pathway affected by talc included cell proliferation, immune responses, and signaling, immunosurveillance, apoptosis." (Emi et al. 2021). These studies provide evidence of chronic inflammation in animals and cells when exposed to talcum powder and support the findings of experiments with Johnson's Baby Powder. (Fletcher et al. 2019).

#### **d) EOC Risk Factors**

Inherited mutations such as BRCA1 and BRCA 2 are the most significant risk factors for epithelial ovarian cancer. The lifetime risk of developing ovarian cancer is 39-46% in BRCA1 carriers and 11-27% in women with BRCA 2 mutation. (Ring et al. 2017). This is compared to 1.3% lifetime risk in non-carriers. Mutations in BRCA1 and BRCA2 make up 75% of all hereditary ovarian cancers, but only account for 10-15% of all EOC. (Lancaster 2015).

Women with hereditary risk are also affected by genetic modifiers, including nongenetic and environmental factors. (Levy-Lahad 2007). Environmental factors would include exposure to talcum powder and asbestos.

Additional risk factors, both nonmodifiable and modifiable, include increasing age, family history of ovarian or breast cancer, nulliparity, early menarche or late menopause, high fat diet, infertility, endometriosis, polycystic ovarian syndrome, hormone replacement therapy, IUD use, history of pelvic inflammatory disease, obesity, and genital use of talcum powder. (Hunn and Rodriguez 2012; Mallen, Townsend, and Tworoger 2018; Park et al. 2018; Folkins et al. 2018; IOM 2016; Lheureux 2019; Phung et al. 2022). Ovarian cancer is often multifactorial; risk factors can be cumulative and synergistic. (Vitonis 2011; Wu 2018).

Multiparity, breast feeding, oral contraceptive use, tubal ligation, salpingoophorectomy, and hysterectomy (without salpingoophorectomy) reduce the risk of developing EOC. (Hunn and Rodriguez 2012; Mallen, Townsend, and Tworoger 2018; Park et al. 2018; Folkins et al. 2018).

#### **e) Talcum Powder, Asbestos and other carcinogens**

During my postgraduate (residency) training (1975-1979) in obstetrics and gynecology it was reported that talc had been identified deeply imbedded in ovarian cancer tissue samples (Henderson 1971) and raised questions about the association between talcum powder and asbestos. In subsequent studies, Henderson confirmed that these findings did not represent surface contamination. (Henderson et al. 1974; Henderson et al. 1979). It seemed plausible that asbestos (a known carcinogen) could be an EOC risk factor. However, we were taught that asbestos had been removed from talcum powder in the production process.

As a young gynecologic oncologist, it was reassuring to learn that asbestos was no longer contained in talcum powder because we knew that asbestos was a potent carcinogen. IARC monograph 100c (2012) clearly summarizes the evidence associating asbestos to mesothelioma and cancer of the lung, larynx, and ovary. Experimental models demonstrate sufficient evidence for the carcinogenicity of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite and anthophyllite) and that all forms, as well as talc containing asbestiform fibers, are carcinogenic to humans. Specifically addressing the increased risk of EOC in women exposed to asbestos in occupational settings, there are at least five cohort mortality studies (Acheson et al. 1982; Wignall and Fox 1982; Germani et al. 1999; Berry, Newhouse, and Wagner 2000; Magnani et al. 2008), two population-based cohort studies (Vasama-Neuvonen et al. 1999; Pukkala et al. 2009) and a case control study (Langseth and Kjaerheim 2004) showing a causal association between exposure to asbestos and ovarian cancer.

In the late 1970s concerns that talc could be associated with EOC were expressed by Woodruff and Longo. (Woodruff 1979). The hypothesis suggested that talc applied to the perineum (vulva) ascends to the vagina and then into the uterus and through the fallopian tubes to implant on the ovary and other peritoneal surfaces. This foreign body was known to create a potent inflammatory reaction when found in the lungs, pleural cavity and peritoneal cavity. In fact, as gynecologic surgeons, we were taught to wash the talcum powder off of our surgical gloves before opening the abdomen to prevent inflammatory reactions and adhesions.

In 1982, a case-control study was the first epidemiologic study alerting the medical community of the possible association of talc use and EOC. (Cramer et al. 1982). Cramer compared women who did and did not use talc in their perineal hygiene. Regular use of talc was found to be associated with an increased occurrence of EOC by 92% (OR of 1.92., 95% confidence interval: 1.27-2.89). Cramer wrote, "It is not clear whether this derives from the asbestos content of talc or from the uniqueness of the ovary which might make it susceptible to carcinogenesis from both talc and other particulates."

Talcum powder also contains other carcinogens including asbestos, talc containing asbestiform fibers (fibrous talc), heavy metals such as nickel, chromium and cobalt (possible 2b), and other



inflammatory agents, toxins, and carcinogens contained in the fragrance chemicals in talcum powder. (Expert Report of Longo and Rigler 2019; Exhibit 28, Deposition of John Hopkins, Ph.D., MDL No. 2378, 2018; Exhibit 47, Deposition of Julie Pier, MDL No. 2738, 2018; Expert Report of Michael Crowley, Ph.D., MDL No. 2738, 2018). In the analysis of historical samples of J&J talcum powder products performed by Drs. Longo and Rigler, asbestos was present in the majority of samples with fibrous talc (talc fibers) seen in virtually all bottles tested. (Longo and Rigler report). In October 2019, FDA found asbestos in a sample of Johnson's Baby Powder purchased online, resulting in Johnson & Johnson recalling one lot of the product – 33,000 bottles. (BMJ 2019).

Fibrous talc (synonymous with talc in an asbestiform habit, asbestiform talc, or talc fibers) and all forms of asbestos are recognized by IARC as carcinogenic to humans, including ovarian cancer. (IARC 2012). According to IARC, consumer products are the primary sources of talc for the general population (non-occupational). Inhalation and perineal application and migration of talcum powders are the primary routes of exposure. (IARC 2012). The carcinogenicity of asbestos and other mineral fibers involves inflammation, oxidative stress, DNA damage and mutation, inducement of cell proliferation and transformation, and resistance to apoptosis. (IARC 2012, Moller 2013, Mossman 2018, Egilman 2019).

#### **f) Epidemiology Studies**

The association of talcum powder and EOC is based on several types of epidemiologic studies. Of course, a randomized controlled double-blinded trial would be more conclusive. However, a randomized trial would be unethical given the evidence that talcum powder causes EOC.

When looking at these epidemiologic studies in their totality, the data shows a consistent, statistically significant increased risk of developing EOC with perineal talcum powder use. Overall, the risk is increased 20-60% when compared with women who did not use talcum powder.

The original case control study published by Cramer et al. in 1982 evaluated the use of perineal talcum powder in 215 white women with EOC (29 cases were "borderline" or ovarian cancer of low malignant potential). These women with EOC were matched by race, age and residence to 215 women in the same community. Talc exposure from surgical gloves, diaphragm use, and perineal use was ascertained. Talc was used by 42.8% of women with EOC and only 28.4% of women who did not have EOC. Any perineal talc exposure showed a statistically significant relative risk of 1.92 (95% confidence limits 1.27-2.89), equivalent to a 92% increased chance of developing EOC. (Cramer et al. 1982).

Subsequently, there have been at least 24 other case-control studies looking at the association of talc and EOC. Overall, the case-control studies show a 30-40% increased risk of EOC associated with genital talcum powder use. These individual studies vary in size and quality, and I weighted them accordingly. Three recent case-control studies replicated previous studies showing an increased risk of EOC in women using perineal talcum powder. Wu evaluated 1701 Californian women with EOC and found talc significantly increased the risk of EOC by 40% in whites, 20% in Hispanics and 56% in African Americans. (Wu et al. 2015). Owing to the small number of

African American women in this study, the findings were not statistically significant.

Subsequently, the National Cancer Institute sponsored a multi-center study of African American women and found a 44% increase in EOC associated with talc use. A dose-response was also found for duration of use and number of lifetime applications ( $p < .05$ ). (Schildkraut et al. 2016). Cramer performed a case control study (with additional pooled data) in 2016 that included nearly 4,000 women with EOC finding an elevated EOC risk of 33% (OR 1.33, 95% CI 1.16, 1.52). Risk increased with frequency and duration of use. (Cramer et al. 2016).

I also reviewed four cohort studies (Gertig, Gates, Houghton, Gonzalez). While not addressing talcum powder usage as the primary research question, these studies also reported the relationship between powder usage and ovarian cancer. The Gertig study showed a statistically significant increased risk of serous epithelial ovarian cancer with talcum powder users. However, I found these studies to have significant limitations due to defective trial design and reporting of their data.

Recently, O'Brien et al. published a pooled study of the data from four cohort studies. The authors concluded that there was not a statistically significant association between the genital use of powder and an increased risk of ovarian cancer. (O'Brien et al. 2020). However, closer examination of the data indicates a significant increased risk in women with an intact reproductive tract. Additional criticisms of the paper are outlined in Letters to the Editor (from Drs. Cramer, Harlow, Murray, and Rothman) and include the possibility of the study being underpowered, the discordance between the findings and conclusions of the authors, the lack of consistency among the cohort inquiries, and the failure to take into account the age and menopausal status of the subjects. (O'Brien et al. 2020; Gossett 2020; Letters to Editor JAMA 2020).

While case-control studies and cohort studies are compelling, in my opinion, meta-analysis studies are much stronger in that they include larger numbers of patients resulting in greater statistical power. I reviewed eight meta-analyses, one pooled study (Terry) and one cohort-only pooled study (O'Brien) reported between 1995 and 2022. All of these studies, with the exception of O'Brien, report a statistically significant increased risk of EOC in women who use talcum powder in the genital area.

Penninkilampi reported that there was a further increase in EOC in women who used talcum powder more frequently. In those who had greater than 3,600 lifetime applications the odds ratio increased to 1.42 (OR 1.42; 95% CI 1.25-1.61) when compared with women who used < 3,600 applications (OR 1.32; 95% CI 1.15-1.50). In this study, talcum powder use was associated with an increased incidence of endometrioid and serous EOC but not mucinous or clear cell types. (Penninkilampi and Eslick 2018). These results were similar to the meta-analysis conducted by Berge et al. (2018), summary relative risk 1.22 (95% CI: 1.13–1.30).

The Taher meta-analysis was commissioned by Health Canada and formed the epidemiological basis for its assessment of the risks of cosmetic talc (non-asbestos containing). Health Canada performed an extensive review of the subject that included a Bradford-Hill analysis and concluded: **“With regards to perineal exposure, analyses of the available human studies in the peer-reviewed literature indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer.** The available data are indicative of a

causal effect. Given that there is potential for perineal exposure to talc from the use of certain self-care products (e.g., body powder, baby powder, diaper and rash creams, genital antiperspirants and deodorants, body wipes, bath bombs, bubble bath), a potential concern for human health has been identified.” (Health Canada Assessment 2021).

In a recent meta-analysis by Davis, et al. (2021), data from five studies in the Ovarian Cancer in Women of African Ancestry Consortium were considered. Participants included 620 African-American ovarian cancer cases and 2,800 white cases, and 1,146 African-American controls and 6,735 white controls who answered questions on genital powder use prior to 2014. For all cases with frequency of use > once per week, there was an increased risk of 1.31 (95% CI 1.15-1.48), with an odds ratio of 1.31 (95% CI 1.13-1.52) for high-grade serous and 1.29 (95% CI 1.09-1.54) for all other histotypes. The authors concluded that “the associations between genital powder use and ovarian cancer risk were similar across race and did not materially vary by histotype.”

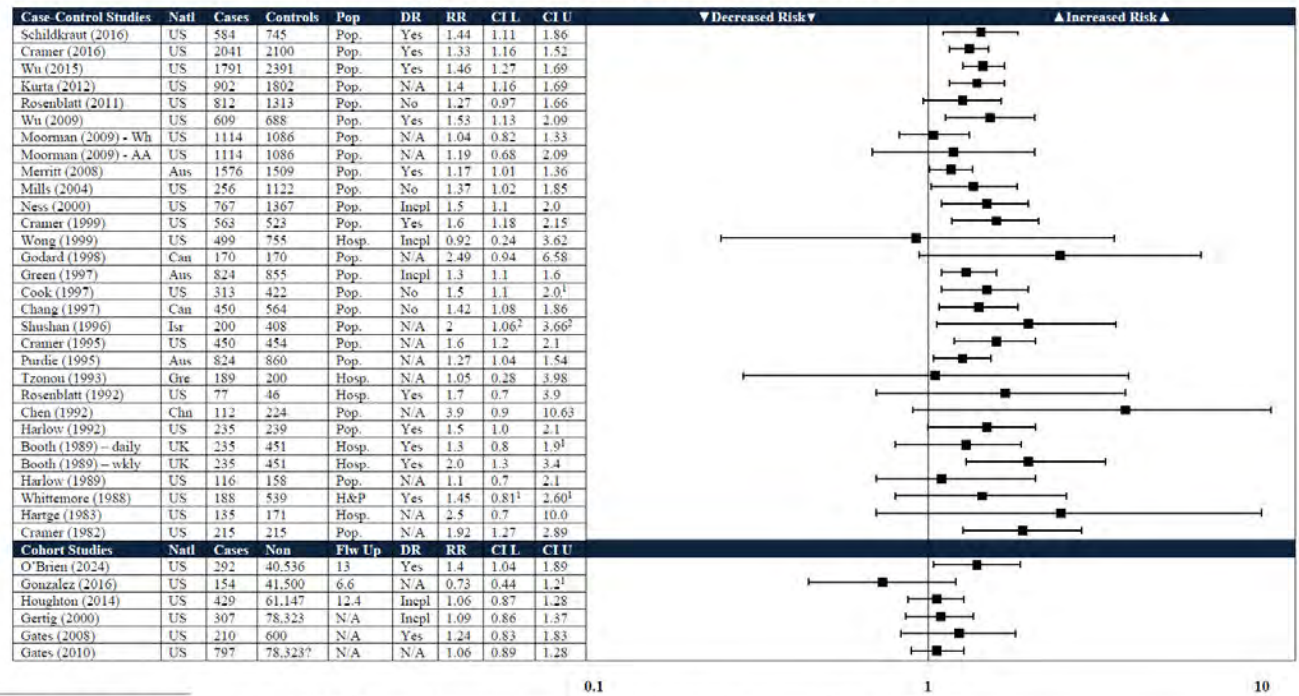
In a study performed by the Ovarian Cancer Association Consortium, the data of 9 case-controlled studies were pooled to consider the effect of well-established ovarian cancer risk factors in women with endometriosis and without endometriosis. The pooled analysis included 8500 women with ovarian cancer and 13,592 controls. For women with endometriosis, an inflammatory process, the increased risk of ovarian cancer with genital talc use was 38% (OR 1.38, 95% CI 1.04-1.84); for women without endometriosis, the increased risk was 12% (OR 1.12, 95% CI 1.01-1.25). (Phung et al. 2022).

Woolen, et al. (2022) conducted a systematic review and meta-analysis of eleven studies, focusing on frequent use of genital talc which was defined as  $\geq 2$  times per week. “Frequent talcum powder use was associated with an elevated risk of ovarian cancer (adjusted pooled summary odds ratio 1.47 (95% CI 1.31, 1.65,  $P < 0.0001$ ).”

With new data from the Sister Study, O’Brien, et al. (2024) published a study showing “in models adjusted for exposure misclassification, genital talc use was positively associated with ovarian cancer (HR range, 1.17-3.34).” Women who used talc frequently had an increased risk of 1.81 (1.29 to 2.53), and women who used genital talc long-term ( $\geq 2$  decades) had an increased risk of 2.01 (1.39 to 2.91). Genital use of talcum powder by women during their 20s resulted in an increased risk of 1.88 (1.37 to 2.57) and for those women who used in their 30s, 2.08 (1.50 to 2.89). For these data points, the study found an increased risk of ovarian cancer with and without correction for recall bias.

In summary, when evaluating all epidemiological studies, there is a consistent and statistically significant increased risk of developing EOC with perineal talcum powder use. Data from the case control, cohort, meta-analysis, and pooled studies are shown in the following forest plots prepared at the direction of Dr. Anne McTiernan:

Figure 2: Case-Control and Cohort Studies



<sup>1</sup> Corrected data-point from study text (report figure: Cook 1997 CI Upper 2.3; Gonzalez CI Upper 1.21; Booth 1989 CI Upper 1.0; Whittemore CI p=0.06).

<sup>2</sup> Corrected data-point from defense expert report(s) (report figure: p=0.04).

## Meta-Analyses and Pooled Studies (All Ovarian)

Meta-Analyses	Studies	Cases	DR	RR	CI L	CI U	▼ Decreased Risk ▼	▲ Increased Risk ▲
Woolen (2022)	11	6542	Yes	1.47	1.31	1.65		
Taher (2018)	27	17,149	Yes	1.28	1.2	1.37		
Penninkilampi (2018)	27	14,311	Yes	1.31	1.24	1.39		
Berge (2018)	27	N/A <sup>1</sup>	Yes	1.22	1.13	1.3		
Langseth (2008)	20	N/A <sup>1</sup>	N/A	1.35	1.26	1.46		
Huncharek (2003)	16	5260	No <sup>2</sup>	1.33	1.16	1.45		
Cramer (1999)	14	3834	N/A	1.4	1.2	1.5		
Gross (1995)	10 <sup>3</sup>	1509	N/A	1.29	1.02	1.63		
Harlow (1992)	6	1106	N/A	1.3	1.1	1.6		
Pooled Meta-Analyses	Studies	Cases	DR	RR	CI L	CI U		
Terry (2013)	8	8,525	Yes	1.24	1.15	1.33		
O'Brien (2020)	4	2168	No	1.08	0.99	1.17		
↳ Patent Reproductive Tract	4	1384	Yes	1.13	1.01	1.26		
Davis (2021)	5	AA:620	No	1.22	0.97	1.53		
		Wh:2800		1.36	1.19	1.57		

0.5

1

2



**g) Migration and transport of talc particles to the ovaries and other pelvic organs**

How is it possible for cosmetic talcum powder, applied to the perineum, to reach the fallopian tube and ovary and cause an inflammatory response that could result in malignant transformation?

As compared to males, the female reproductive tract is open and allows migration of potential pathogens into the peritoneal cavity. The female reproductive tract is in continuity between the peritoneal cavity and the external environment. For example, an ovum extruded from the ovary (an intraperitoneal organ) can progress down the fallopian tube to the uterine cavity, implant and result in a pregnancy that delivers vaginally. The converse is also obvious. It is clearly recognized that sperm (including sperm and sperm particles which would be non-motile) ascend from the vagina through the uterus and into the fallopian tube and into the peritoneal cavity. (Jones and Lopez 2006). Sexually transmitted bacterial infections (for example, gonorrhea and chlamydia) ascend from the vagina to the tube and ovary resulting in pelvic inflammatory disease and tubo-ovarian abscesses. While sperm and bacteria are “motile”, non-motile substances have been demonstrated to ascend from the vagina to the peritoneal cavity. As far back as 1961, Egli demonstrated that carbon particles placed in the posterior vaginal fornix were observed in the fallopian tubes within less than one hour in two of three patients tested. (Egli and Newton 1961). Venter and Iturralde placed albumin microspheres labelled with 99mTc into the vagina. (Venter and Iturralde 1979). During pelvic surgery the following day, radioactive levels were found in the tubes and ovaries in nine of 14 cases. Sjösten conducted a trial that showed that powder on gloves used to perform a gynecologic exam resulted in powder detected in the peritoneal fluid, tubes and ovaries one day after the examination. (Sjösten, Ellis, and Edelstam 2004). Likewise, talc has been detected on the ovaries following surgical oophorectomy. (Henderson et al. 1971; Heller, Gordon, et al. 1996; Heller, Westhoff, et al. 1996). In a recent study using correlative light and scanning electron microscopy, morphologically demonstrated talc particles were found in multiple pelvic organ sites, including pelvic tissues and lymph nodes simultaneously. (McDonald 2019). Talc particles and fibers found in pelvic tissues have been shown to be similar to those found in cosmetic talcum powder products, further supporting migration and transport to pelvic organs. (Johnson 2020).

I reviewed the small body of literature suggesting that migration of particles does not occur and do not think these studies are compelling.

I believe that ascension of talcum powder and its constituents through the genital tract is the most important route of exposure. However, inhalation is another plausible mechanism. (IARC 2012; Steiling et al. 2018, Steffen et al. 2020; Health Canada 2021). With either route, at least some of the talcum powder components are likely to be absorbed into the lymphatic system and bloodstream, representing another mechanism for exposure to internal organs.

**CAUSATION ANALYSIS**

In my opinion, genital application of talcum powder is a significant risk factor for all users and can cause epithelial ovarian cancer in some women by an accepted mechanism. As an academic and practicing physician, I made this determination in the context of Bradford Hill considerations as follow:

**Strength and consistency:** This opinion is supported by overwhelming epidemiologic evidence showing that the genital use of talcum powder statistically increases a woman's risk of developing EOC by approximately 30 percent (OR 1.31 Penninkilampi 2018; OR 1.28 Taher et al. 2019; OR 1.31 Davis et al. 2021). For frequent users of talcum powder, the risk is higher (e.g., Woolen et al. 2022; O'Brien et al. 2024). All previous meta-analyses reported similar increases in the risk of developing EOC with the use of talcum powder. In my view, especially when considering the severity and frequency of ovarian cancer and the preventable nature of talcum powder usage, this finding is critically important and consistently supported by numerous studies.

**Specificity:** Based on the epidemiologic studies cited in this report, there appears to be a specific ovarian cancer caused by talcum powder: epithelial ovarian cancer (EOC). Other reproductive cancers do not appear to have an association. This association satisfies this consideration, although I did not weigh this factor to be as important as strength and consistency.

**Temporality:** In many cancers where there are identified etiologic agents (smoking and lung cancer, HPV infection and cervical cancer) there is a latency period (time from exposure to the onset of the cancer) that can extend over decades. (Nadler and Zurbenko 2014). This concept applies to the latency period of talcum powder use before a woman develops ovarian cancer, thus fulfilling this consideration.

**Biologic Gradient/Dose-response:** Measuring the "dose" of talcum powder used by an individual woman is difficult to ascertain and has been dependent on recall by the woman. In general, studies have attempted to capture the application "frequency" (daily? Only used on perineal pads during menstrual cycle?) or duration of use (how many years?). In addition, biologic gradient or dose-response is not always linear (e.g., asbestos exposure and mesothelioma is generally thought to have a "threshold response"). A number of studies have demonstrated an association between "dose" and the occurrence of EOC (response). (Terry et al. 2013; Schildkraut et al. 2016; Daniel W. Cramer et al. 2016; Penninkilampi and Eslick 2018; Woolen et al. 2022). More recently, *in vitro* studies have demonstrated a dose dependent effect of talcum powder on molecular changes associated with carcinogenesis. (Fletcher et al. 2019; Mandarino et al. 2020).

**Plausibility:** This is obviously a critical factor when forming opinions on causation of a risk factor. Evidence shows that talcum powder ascends from the perineum through the vagina, cervix and uterus into the fallopian tubes and onto the ovary. Talcum powder is known to be an agent that causes inflammation. An inflammatory reaction caused by talcum powder on the tube and surface of the ovary results in genetic mutations and carcinogenesis. Talcum powder causes ovarian cancer through this mechanism. The "talcum powder agent" includes numerous constituents such as platy talc, asbestos, fibrous talc, heavy metals and/or chemicals contained in fragrances added to talcum powder, all of which cause an inflammatory reaction leading to carcinogenesis.

**Coherence:** Epidemiological data, *in vitro* and *in vivo* research are consistent in explaining the pathogenesis of EOC through the inflammatory mechanisms described above. (Saed, Diamond, and Fletcher 2017; Savant et al. 2018; Ding et al. 2021). Further, this is consistent with the causes of other cancers.



**Experiment:** There are no randomized trials comparing outcomes of women who use or who do not use talcum powder in their perineal hygiene. Further, such a trial at this point in time would be unethical. How could we expose women to talcum powder when the existing evidence supports causation of EOC? Laboratory research (*in vitro*) present evidence to support the biologic, genetic, epigenetic and neoplastic consequence to ovarian epithelium when exposed to talcum powder. (Buz'Zard and Lau 2007; Shukla et al. 2009; Akhtar et al. 2010; Akhtar et al. 2012; Fletcher et al. 2019; Mandarino et al. 2019; Emi et al. 2021; Harper et al. 2023).

**Analogy:** There are numerous reports in the medical literature of minerals similar to talc causing cancer. Probably the most significant example is asbestos and lung cancer (mesothelioma).

## CONCLUSION

It is my opinion, based on research that I have conducted in the medical and scientific literature as well as my knowledge and experience as an obstetrician-gynecologist and as a subspecialist in gynecologic oncology for over 40 years, that the use of talcum powder products including Johnson's Baby Powder and Shower to Shower, applied to the genital area of women, can cause EOC. The mechanism by which talcum powder causes cancer involves: 1) ascension of particles to the fallopian tubes and ovaries and 2) initiation of an inflammatory process that includes oxidative stress and specific genetic mutations. The additional studies that have been published and I have considered since my prior report reaffirm my opinion that the genital use of talcum powder can cause ovarian cancer.

These opinions are made to a reasonable degree of medical and scientific certainty.

I reserve the right to supplement or amend this report if new information becomes available. I reserve the right to review and remark on the reports and testimony of Defendants' experts. My prior testimony is attached as **Exhibit C**.

**Hilary Converse: Brief Medical History**  
**DOB [REDACTED] 1948**

**Initial Presentation:**

In June 2007, Ms. Converse, then a 58 year-old woman, [REDACTED]  
[REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**Staging Procedure:**

[REDACTED]

[REDACTED]

**Pathology Report:**

[REDACTED]

[REDACTED]

**Postoperative Treatment:**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**Hilary Converse: Case-specific opinions**

I reviewed the available medical records for Ms. Hilary T. Converse, deposition testimony, Plaintiff Profile Form and Dr. Godleski's expert report, in considering my opinion regarding causation in this case. My opinions are based on my education, training, and experience, as well as the General Causation facts and opinions contained in this report. After completing my review, it is my opinion that Ms. Converse's regular use of talcum powder products on her body, including her genital area, is a substantial contributing cause of her ovarian cancer.

Hilary Converse was found to have a Stage IaG3 Clear Cell carcinoma of the ovary. She underwent [REDACTED]

[REDACTED]

In formulating my opinion regarding causation of Ms. Converse's ovarian cancer, I considered all the relevant factors that could contribute to the development of her ovarian cancer, forming a differential diagnosis as follows:

1. Is the genital use of talcum powder associated with Ms. Converse's type of ovarian cancer? Yes, clear cell carcinoma was confirmed by pathology and is one of the histologic subtypes associated with genital talcum powder use in multiple studies.
2. Did the plaintiff have a history of sufficient perineal use of talcum-containing products? Ms. Converse testified in her deposition that she used Johnson's Baby Powder [REDACTED]  
[REDACTED]  
[REDACTED] She did not use any other talcum powder products.
3. Was there talc and/or asbestos found in her pathologic tissue, providing additional evidence of usage? Although not a requirement, the presence of talc particles or mineral fibers in pathology lends support to causation. Dr. Godleski in his pathologic evaluation found 4 talc particles in cervix tissue and lymph nodes.
4. Was there enough time between the onset of use and the diagnosis of ovarian cancer to account for the expected latency period associated with the development of ovarian cancer? Yes, she reports use beginning approximately 45 years prior to the diagnosis of her ovarian cancer - consistent with the latency period described with other carcinogens causing cancer and talcum powder use causing ovarian cancer.

5. Were other risk factors or protective factors present and, if so, what was their contribution to the development of ovarian cancer?

Risk Factors:

- Inherited genetic mutations – [REDACTED].
- Family history of ovarian or breast cancer – [REDACTED].
- Increasing age – Ms. Converse was 58 at the time of diagnosis, which is slightly younger than the average age of 63 years.
- Nulliparity – Ms. Converse is [REDACTED].
- Early menarche – Ms. Converse testified [REDACTED].
- Late menopause – Ms. Converse [REDACTED].
- High fat diet – [REDACTED].
- Infertility – [REDACTED].
- Endometriosis – [REDACTED].
- Polycystic ovarian syndrome – [REDACTED].
- Hormone replacement therapy – [REDACTED].
- IUD use – [REDACTED].
- Pelvic Inflammatory Disease – [REDACTED].
- Obesity - [REDACTED] se.

Protective Factors:

- Multiparity – [REDACTED].

- Breastfeeding – [REDACTED] n.
- Oral contraceptive use – [REDACTED].
- Tubal ligation – [REDACTED].
- Hysterectomy – [REDACTED].

In summary, after reviewing the available medical records, Plaintiff Profile Form, deposition testimony, and Dr. Godleski's expert report, it is my opinion that Ms. Converse's long-term genital use of Johnson's Baby Powder and [REDACTED] are substantial contributing causes of her ovarian cancer. My opinions are made to a reasonable degree of medical and scientific certainty. I reserve the right to update this report if new information becomes available. I also reserve the right to review and remark on the reports and testimony of Defendants' experts.



# Exhibit A

**Updated: March 2023****UNC SCHOOL OF MEDICINE  
CURRICULUM VITAE****Personal Information****Name:** Daniel Lyle Clarke-Pearson, M.D.**Address:** 105 Porter Place  
Chapel Hill, NC 27514861 Skin Camp Creek  
Road  
Todd, NC 28684**Phone:** (919) 215-9561**Education and Training**

Fellow	Duke University Medical Center	1979-1981	Gynecology Oncology
Residency	Duke University Medical Center	1975-1979	Obstetrics and Gynecology
Medical Degree	Case Western Reserve University School of Medicine	1971-1975	Medicine
Bachelor of Arts	Harvard College	1966-1970	Biology

**Professional Experience**

Professor	University of North Carolina, Chapel Hill	July 2019-present	Obstetrics and Gynecology Division of Gynecologic Oncology
Active Consulting Staff	The Outer Banks Hospital	Oct 2009 – 2012	Medicine/Oncology Section
Chairman	University of North Carolina at Chapel Hill School of Medicine	September 2005 – July 2019	Obstetrics and Gynecology
Robert A. Ross Distinguished Professor	University of North Carolina at Chapel Hill School of Medicine	September 2005 – July 2019	Obstetrics and Gynecology

James M. Ingram Professor of Gynecologic Oncology	Duke University Medical Center	July 1993-2005	Gynecologic Oncology
Division Director	Duke University Medical Center	July 1987-2005	Gynecologic Oncology
Professor	Duke University Medical Center	July 1987-2005	Obstetrics and Gynecology
Director of Gynecology and Gynecologic Oncology	University of Illinois at Chicago	January 1985-1987	Obstetrics and Gynecology
Associate Professor	University of Illinois at Chicago	July 1984-1987	Obstetrics and Gynecology
Associate Professor	Duke University Medical Center	January 1984	Obstetrics and Gynecology
Co-Director, Trophoblastic Disease Center	Duke University Medical Center	July 1982-1984	Obstetrics and Gynecology
Assistant Professor	Duke University Medical Center	July 1980-1984	Obstetrics and Gynecology

### **Honors and Awards**

2022	President-elect, Society of Pelvic Surgeons
2022	Distinguished Service Award, North Carolina Obstetrics and Gynecology Society
2019	UNC Lifetime Achievement Award for Medical Student Education
2009-2010	President, Society of Gynecologic Oncologists
2001-2020	America's Top Doctors for Women (176 Physicians): Women's Health
2008	CREOG National Faculty Award for Excellence in Resident Education
2004	Invited Panel Member, International Consensus Conference of the Prevention of Venous Thromboembolism, Windsor, England
2002	ACOG Roy Pitkin/Elsevier Award: One of top four papers published annually in <u>Obstetrics and Gynecology</u>
2001-present	America's Top Doctors for Women: Women's Health

- 1991                      Invited Panel Participant, Consensus Meeting on the Prevention of  
Thromboembolism - Windsor, England
- 1985                      Clinical Research Prize Paper – ACOG District Meeting
- 1981-1984                Junior Faculty Clinical Fellowship – American Cancer Society
- 1982                      Donald F. Richardson Memorial Prize Paper -Best research paper presented by  
a Junior Fellow at a District ACOG Meeting
- 1981                      Clinical Research Paper, Second Place  
ACOG Annual Clinical Meeting
- 1981                      Junior Fellow First Prize Paper – ACOG District IV
- 1980                      American Cancer Society Clinical Fellow
- 1979                      Junior Fellow First Prize Paper – ACOG District IV

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### Original Research

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5. Rossi E, **Clarke-Pearson DL**. Screening for Ovarian Cancer in Midlife Women. *The Female Patient*. 2011; 36: 37-40.
6. **Clarke-Pearson DL**. Clinical practice. Screening for ovarian cancer. *N Engl J Med*. 2009; 361(2):170-7
7. Alvarez A, **Clarke-Pearson DL**. Platinum-Resistant and Refractory Ovarian Cancer: Second-Line Treatment Options. *Am J Cancer* 2003; 2: 1-13.
8. Soper JT, Evans AC, Conaway MR, **Clarke-Pearson DL**, Berchuck A, Hammond CB: Evaluation of prognostic factors and staging in gestational trophoblastic tumor. *Gest Tropho Tumor* 84(6):969-973, 1994.
9. Woolas R, Xu FJ, Jacobs IJ, Yu YH, Daly L, Berchuck A, Soper JT, **Clarke-Pearson DL**, Oram DH, Bast RC Jr: Screening strategies for ovarian cancer. *Diag Oncol* 3:287-293, 1993.

10. Nicholaides AN, Areelus J, Belcaro G, Bergqvist D, Borris LC, Buller HR, Caprini JA, Christopoulos D, **Clarke-Pearson D**, et al: Prevention of venous thromboembolism: European consensus statement. *Int Angiology* II:151-159, 1992.
11. **Clarke-Pearson DL**, Hume RF: Venous thromboembolic disease in Obstetrics and Gynecology: Prevention, diagnosis and treatment. *Curr Probl Obstet Gynecol Fertil* 12:38-63,1989.
12. **Clarke-Pearson DL**, Olt G: Thromboembolism in patients with gynecologic tumors: Risk factors, natural history and prophylaxis. *Oncol* 3:39-44, 1989.
13. Beckmann CRB, **Clarke-Pearson DL**, Evenhouse R: A reusable plastic training model for teaching Papanicolaou smear technique. *Am J Obstet Gynecol* 157:259-260, 1987.
14. Creasman WT, **Clarke-Pearson DL**, Ashe CA, Weed JC Jr: The abnormal pap smear: What to do next. *Cancer* 48:515, 1981.

**ACOG Committee Opinions published during tenure as ACOG Gynecologic Management Committee Chair:**

1. Performance enhancing anabolic steroid abuse in women. Committee Opinion No. 484. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011;117:1016–18.
2. Understanding and using the U.S. Medical Eligibility Criteria for Contraceptive Use, 2010. Committee Opinion No. 505. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011;118:754–60.
3. Expedited partner therapy in the management of gonorrhea and chlamydia by obstetrician–gynecologists. Committee Opinion No. 506. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011;118:761–6.
4. Management of vulvar intraepithelial neoplasia. Committee Opinion No. 509. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011;118:1192–4.
5. Vaginal placement of synthetic mesh for pelvic organ prolapse. Committee Opinion No. 513. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011;118:1459–64.
6. Compounded bioidentical menopausal hormone therapy. Committee Opinion No. 532. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2012;120:411–5.
7. Well-woman visit. Committee Opinion No. 534. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2012;120:421–4.
8. Reprocessed single-use devices. Committee Opinion No. 537. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2012;120:974–6.
9. Risk of venous thromboembolism among users of drospirenone-containing oral contraceptive pills. Committee Opinion No. 540. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2012;120:1239–42.
10. Over-the-counter access to oral contraceptives. Committee Opinion No. 544. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2012;120:1527–31.
11. Postmenopausal estrogen therapy: route of administration and risk of venous thromboembolism. Committee Opinion No. 556. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2013;121:887–90.

12. Management of acute abnormal uterine bleeding in nonpregnant reproductive-aged women. Committee Opinion No. 557. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:891–6.
13. Integrating immunizations into practice. Committee Opinion No. 558. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:897–903.

#### **Developed during tenure as Committee Chair:**

1. Female age-related fertility decline. Committee Opinion No. 589. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:719–21.
2. Hormone therapy and heart disease. Committee Opinion No. 565. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:1407–10.
3. Professional liability and gynecology-only practice. Committee Opinion No. 567. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;122:186.
4. Solutions for surgical preparation of the vagina. Committee Opinion No. 571. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;122:718–20.
5. Understanding and using the U.S. Selected Practice Recommendations for Contraceptive Use, 2013. Committee Opinion No. 577. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;122:1132–3.
6. Von Willebrand disease in women. Committee Opinion No. 580. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;122:1368–73.
7. Addressing health risks of noncoital sexual activity. Committee Opinion No. 582. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;122:1378–83.

#### **Editorials and Letters**

1. **Clarke-Pearson DL**, Geller EJ. Complications of Hysterectomy. Obstet Gynecol 2013; 121:1-21.
2. **Clarke-Pearson DL**. Thromboprophylaxis in Gynecologic Surgery: Why are we Stuck in 1975? Obstet Gynecol 2011; 118: 973.
3. Martino M, Rajaram L, Maxwell GL, **Clarke-Pearson DL**. Combination Prophylaxis for Thromboembolism Prevention among Gynecologic Oncology Patients Perioperatively. (Letter) Gynecol Oncol 2008; 109: 426-27.
4. **Clarke-Pearson DL**: Prevention of venous thrombosis following gynecologic Surgery. J Gynecol Tech 1(1):11-17, 1995.
5. **Clarke-Pearson DL**: Crafting the operative note: techniques critical to success (editorial). J Gynecol Tech 1(3):119-120, 1995.
6. **Clarke-Pearson, DL**: Reassessment of ovarian cancer: What are our goals? Gynecol Oncol 52:151-153, 1994.
7. Soper JT, **Clarke-Pearson DL**, Berchuck A: The clinical significance of blood transfusion at the time of radical hysterectomy. (Letter). Obstet Gynecol 77:165, 1991.



8. **Clarke-Pearson DL:** The importance of calf vein thrombosis. N Eng J Med 302:752, 1980.

#### Published Abstracts

1. Barber EL, **Clarke-Pearson DL.** Risk of venous thromboembolism in minimally invasive versus open hysterectomy for endometrial cancer. SGO Annual Meeting 2016.
2. Barber EL, Gehrig PA, **Clarke-Pearson DL.** A risk assessment score for postoperative VTE among patients undergoing minimally invasive surgery for gynecologic cancer. SGO Annual Meeting 2016.
3. Barber EL, **Clarke-Pearson DL.** Validity of currently available venous thromboembolism risk scores among gynecologic oncology patients.
4. Look K, Brunetto VL, **Clarke-Pearson DL,** Averette H, Major FJ, Alvarez RD, Homesley HD, Zaino R: An analysis of cell type in patients with surgically stages stage IB carcinoma of the cervix: A Gynecologic Oncology Group (GOG) Study. Abstract. Gynecol Oncol 60:117, 1996.
5. Omura GA, Blessing J, Vaccarello L, Berman M, Mutch D, **Clarke-Pearson DL,** Anderson B: A randomized trial of Cisplatin versus Cisplatin + Mitolactol versus Cisplatin + Ifosfamide in advanced squamous carcinoma of the cervix by the Gynecologic Oncology Group (GOG). Abstract. Gynecol Oncol 60:120, 1996.
6. Omura GA, Blessing J, Vaccarello L, Berman M, Mutch D, **Clarke-Pearson DL,** Anderson B: A randomized trial of Cisplatin versus Cisplatin + Mitolactol versus Cisplatin + Ifosfamide in advanced squamous carcinoma of the cervix by the Gynecologic Oncology Group (GOG). Abstract. ASCO, 1995.
7. Alberts DS, Liu PY, Hannigan EV, O'Toole R, Williams SD, Vogel S, Franklin FW, **Clarke-Pearson DL,** Malviya VK, Dubeshter B, Hoskins W, Adelson M, Alvarez RD, O'Sullivan J, Garcia DJ, Sparks D, Rothenberg ML: Phase III study of intraperitoneal (IP) Cisplatin CDDP/Intravenous (IV) Cyclophosphamide (CPA) vs. IV CDDP/IV CPA in patients (Pts) with optimal disease stage III ovarian cancer: A SWOG-GOG Intergroup Study. Abstract. ASCO, 1995.
8. Stehman FB, Bundy BN, Ball H, **Clarke-Pearson DL:** Sites of failure and times to failure in carcinoma of the vulva treated conservatively: A Gynecologic Oncology Group Study. Abstract. AGOS 1995.
9. Omura GA, Blessing J, Vaccarello L, Berman M, Mutch D, **Clarke-Pearson D,** Anderson B: A randomized trial of cisplatin versus cisplatin + mitolactol (CM) versus cisplatin + ifosfamide (CIFX) in advanced squamous carcinoma of the cervix (SCC) by the Gynecologic Oncology Group (GOG). Presented at the 1995 American Society of Clinical Oncology Annual Meeting.
10. **Clarke-Pearson DL,** Berchuck A, Kohler M, Rodriguez GC: Retroperitoneal drains/morbidity of nodes. Society of Gynecologic Oncologists, 1993.
11. Hoskins WJ, McGuire WP, Brady MS, Copeland L, Homesley HD, **Clarke-Pearson DL:** Serum CA-125 for prediction of progression in advanced epithelial ovarian carcinoma (AOC). The Gynecologic Oncology Group (GOG). Proc ASOC (Abstract #707) 11:223, March 1992.
12. McGuire WP, Hoskins WJ, Brady MF, Homesley HD, **Clarke-Pearson DL:** A Phase III trial of dose intensive (DI) cisplatin (CDDP) and Cytosan (CTX) in advanced ovarian cancer (AOC). Proc ASCO, March 1992.
13. Hoskins WJ, McGuire WP, Brady MS, Homesley HD, **Clarke-Pearson DL:** Serum CA-125 for prediction in advanced epithelial ovarian cancer (AOC). The Gynecologic Oncology Group (GOG).



Third Meeting of the International Gynecologic Cancer Society, September 22-26, 1991, Cairns, Australia.

14. McGuire WP, Hoskins WJ, Brady MS, Homesley HD, **Clarke-Pearson DL**: A Phase II trial of dose intense (DI) versus standard dose (SD) Cisplatin (CDDP) and Cytosin (CTX) in advanced ovarian cancer (AOC). The Gynecologic Oncology Group (GOG). Third Meeting of the International Gynecologic Cancer Society, September 22-26, 1991, Cairns, Australia.
15. Shpall E, **Clarke-Pearson DL**, Soper JT, Berchuck A, Jones R, Bast R, Lider Y, Vanacek K, Tyler T, Peters W: High dose alkylating agent chemotherapy with autologous bone marrow support in patients with Stage III/IV epithelial ovarian cancer. Society of Gynecologic Oncologists, 1990.
16. Soisson AP, Soper JT, Berchuck A, Creasman WT, **Clarke-Pearson DL**: The role of radiation therapy following radical hysterectomy for carcinoma of the cervix. Society of Gynecologic Oncologists, 1989.
17. Berchuck A, Soisson AP, Soper JT, **Clarke-Pearson DL**, McCarty KS Jr, Bast RC Jr: Cellular expression of CA-125 and metastatic potential of endometrial adenocarcinoma. Society of Gynecologic Oncologists, 1989.
18. Soisson AP, Berchuck A, Soper JT, **Clarke-Pearson DL**, Flowers J, Kinney R, McCarty KSJR, Bast RC Jr: TAG-72 expression in benign and malignant endometrium. American College of Obstetricians and Gynecologists, Armed Forces District Meeting, 1988.
19. Christensen C, McCarty KS Jr, Flowers J, Soper JT, McCarty KS Sr, **Clarke-Pearson DL**: Progesterone receptor in ovarian carcinoma: Comparison of biochemical and immunohistochemical techniques. American College of Obstetricians and Gynecologists, Annual Clinical Meeting, 1988.
20. Jenkins SM, Sotsman HD, Spritzer CE, Herfkens RJ, Carroll BA, Kadir S, **Clarke-Pearson DL**, Coleman RE: Diagnosis of deep venous thrombosis: Comparison of venography with four noninvasive techniques. The Radiological Society of North America, 1988.
21. Mutch DG, Soper JT, Babcock CJ, Christensen CW, **Clarke-Pearson DL**, Hammond CB: Recurrent gestational neoplasia: Experience of the Southeastern Trophoblastic Disease Center. Abstract, Gynecol Oncol 29:133, 1988.
22. Christensen C, McCarty KS Jr, Flowers J, Soper JT, McCarty KS Sr, **Clarke-Pearson DL**: Analysis of estrogen receptor in ovarian carcinoma using biochemical and monoclonal antibody assays. Presented at American College of Obstetricians and Gynecologists District IV Meeting. Atlanta, Georgia, October 1987.
23. **Clarke-Pearson DL**, Creasman WT: Prevention of postoperative deep venous thrombosis by two intense low-dose heparin regimens: A controlled trial. Abstract, Society of Pelvic Surgeons, 1986.
24. **Clarke-Pearson DL**, DeLong ER, Synan IS, Coleman RE, Creasman WT: Variables associated with postoperative deep venous thrombosis. Abstract, Society of Gynecologic Investigation, p. 119, 1986.
25. Siegel RS, Kessler CM, **Clarke-Pearson DL**, Barth S, Fortune W, Reba R, Coleman RE: Application of Indium-111-labeled donor platelets to detection of deep venous thrombosis. Clin Res 32:323A, 1984.
26. Creasman WT, Henderson D, **Clarke-Pearson DL**: Use of estrogens after treatment for adenocarcinoma of the endometrium. Gynecol Oncol 17:2, p. 255, 1984.
27. Siegel RS, **Clarke-Pearson DL**, Barth S, Fortune W, Lewis RJ, Reba R, Coleman RE: Application of Indium-111-labeled donor platelets to detection of deep venous thrombosis and monitoring clot

resolution on streptokinase therapy. Blood, Suppl 62:310,1983.

28. Siegel RS, **Clarke-Pearson DL**, Coleman RE: Indium-111-labeled platelets in the detection of deep venous thrombosis and pulmonary embolism. Blood 50:223, 1982.
29. Postoperative thromboembolism prophylaxis in gynecologic oncology: A prospective, controlled trial of low-dose heparin and external pneumatic calf compression. Gynecol Oncol, 1982.

### Un-refereed Publications

1. **Clarke-Pearson DL.** Prevention and Management of Venous Thromboembolism (15 minute Video) for the Globathon to End Women's Cancer. September 2014.
2. **Clarke-Pearson DL,** Brincat C, Tang J. Prevention and Management of Venous Thromboembolism in Gynecologic Surgery. ACOG Update. Vol 37, No 2. August, 2011.
3. **Clarke-Pearson DL.** Preventing Venous Thromboembolism: Evidence-based Perioperative tactics. OBG Management. 2006, 18: 56-66.
4. **Clarke-Pearson DL:** Prevention of venous thrombosis following gynecologic surgery in menopausal patients. Menopausal Medicine Vol 4 (4):6-9, 1996.
5. Rodriguez GC, **Clarke-Pearson DL:** What is the appropriate preoperative and prenatal screen for hemostatic disorders? Obstet Gynecol Forum, November 1991.
6. **Clarke-Pearson DL,** Hume RF: Venous thromboembolic disease in obstetrics and gynecology: Prevention, diagnosis and treatment. Curr Problems in Obstet Gynecol, 1989.
7. Hunter VJ, Christensen C, **Clarke-Pearson DL:** Evaluation and management of the abnormal Papanicolaou smear. North Carolina Family Physician, 1989.
8. **Clarke-Pearson DL,** Krumholz AB: When the pap smear is equivocal. Patient Care 23:43-47, 1989.
9. **Clarke-Pearson D,** DiSaia P, Mastroianni L, Richart R, Weingold AB: Advances in managing endometrial carcinoma. Patient Care 22:102-116, 1988.
10. Creasman WT, Smith EB, **Clarke-Pearson DL:** Current concepts of gestational trophoblastic disease. Female Patient, 1984.
11. Creasman WT, **Clarke-Pearson DL:** Abnormal cervical cytology: Spotting it, treating it. Contemporary Obstet Gynecol 21:53-76, 1983.
12. Hammond CB, **Clarke-Pearson DL,** Soper JT: Management of patients with gestational trophoblastic neoplasia: Experience of the Southeastern Regional Center. In: The Proceedings of the World Congress on Gestational Trophoblastic Neoplasia, Nigeria, 1982.
13. **Clarke-Pearson DL:** Application of impedance phlebography in obstetrics. Symposium on Noninvasive Diagnostic Techniques in Vascular Disease. San Diego, California, 1979.
14. **Clarke-Pearson DL:** The O.S.R. as an influence to health education. The Scalpel, Journal of Alpha Delta Alpha Medical Honor Society, 1975.

### Teaching Record

- 2022 Society of Pelvic Surgeons Annual Meeting: Panel Moderator- "Where are the limits to cancer excision and reconstruction?"
- 2020 George Washington University Medical Oncology Board Review Course (Faculty) "Cervix, vulva vagina cancer and gestational trophoblastic disease" (by zoom)
- 2019 Presidential Speaker, South Atlantic Association of ObGyn Annual meeting, Sea Island Georgia

George Washington University Medical Oncology Board Review Course (Faculty) “Cervix, vulva vagina cancer and gestational trophobalastic disease”

- 2018 Visiting Professor, University of West Virginia, Morganton, WV  
Antonio Palladino Lectureship

George Washington University Medical Oncology Board Review Course (Faculty) “Cervix, vulva vagina cancer and gestational trophobalastic disease”

- 2016 Plenary Session, Society of Pelvic Surgeons, St Louis, Mo. “Venous Thromboembolism: Minimally Invasive Compared with Open Hysterectomy for Endometrial Cancer”  
Key Note Speaker. ACOG Armed Forces District Meeting, Orlando, FL
- Visiting Professor and Research Day Judge, Cleveland Clinic Department of Obstetrics and Gynecology and Women’s Research Institute, Cleveland, Ohio
- Visiting Professor, Department of Obstetrics and Gynecology, Carilion Roanoke Memorial Hospital, Roanoke, Va.

George Washington University  
Medical Oncology Board Review Course (Faculty) “Cervix, vulva vagina cancer and gestational trophobalastic disease”

- 2015 Visiting Professor  
University of Michigan

George Washington University  
Medical Oncology Board Review Course (Faculty)

- 2014 Visiting Professor  
Massachusetts General Hospital, ObGyn Department Grand Rounds Boston, MA  
Invited speaker: ACOG District II Annual Meeting, New York City “Uterine Morcellation: A Decision Analysis”

George Washington University Medical Oncology Board Review Course (Faculty) “Cervix, vulva vagina cancer and gestational trophobalastic disease”

- 2013 Visiting Professor and Resident Research Day Judge  
Department of Obstetrics and Gynecology, University of Nebraska Omaha, NE  
Visiting Professor, Emory University Department of Obstetrics and Gynecology Atlanta, GA

Key Note Speaker: Inaugural Ireland Ovarian Cancer Forum “Surgery for Ovarian Cancer”  
Dublin, Ireland

Panel Moderator, American College of Surgeons Annual Clinical Congress “General Surgery in the Pregnant Patient” Washington, DC

George Washington University  
Medical Oncology Board Review Course (Faculty)

- 2012 Clifford Wheless Lectureship, Johns Hopkins University, Department of Obstetrics and Gynecology, Baltimore, MD

Panel Moderator, American College of Surgeons Annual Clinical Congress “Multidiciplinary approach

to Vaginal Fistula” Chicago, IL

Resident Research Day Judge and Visiting Professor  
Department of Obstetrics and Gynecology, Greenville Hospital System, Greenville, SC

Visiting Professor: University Teaching Hospital, Department of Obstetrics and Gynecology, Lusaka, Zambia

Cervical Cancer management  
Current Treatment of Vulvar Carcinoma

Visiting Professor: Center for Infectious Disease Research in Zambia (CIDRZ), Lusaka, Zambia

Human Papilloma Vaccine for the Prevention of Cervical Cancer

Visiting Professor: Inova Fairfax Hospital Women’s Center, Fairfax VA

Visiting Professor: Emory University School of Medicine, Department of Obstetrics and Gynecology.  
Atlanta, GA

George Washington University  
Medical Oncology Board Review Course (Faculty)

- 2011 Sloane Symposium: Current Issues and Controversies in Obstetrics and Gynecology Columbia University, College of Physicians and Surgeons, Department of Obstetrics and Gynecology  
Vandewiele Lecturer: “Prevention of Venous Thromboembolism in Gynecologic Surgery”  
Guest Lecturer and Judge: Resident Research Day, Columbia University “What to say in your Operative Note”

University of Kentucky: Residents’ Research Day Speaker  
Virginia Commonwealth University School of Medicine. Department of Obstetrics and Gynecology  
Annual Ware-Dunn Symposium Keynote speaker

George Washington University  
Medical Oncology Board Review Course (Faculty)

**2010** New England Obstetrical and Gynecological Society, Sturbridge, MA  
Invited Speaker

ACOG Annual Clinical Meeting, San Francisco, CA  
Luncheon Seminar Leader

George Washington University Medical Oncology Review Course  
Washington, DC  
Invited Faculty

MD Anderson Cancer Center Medical Oncology Review Course  
Houston, TX  
Invited Faculty

The Society of Gynecologic Oncology of Canada  
Royal College of Physicians and Surgeons of Canada  
Annual Meeting  
Invited Lecturer: Thromboprophylaxis in Minimally Invasive Surgery

Visiting Professor  
University of South Florida, Tampa, FL

**2009** Resident Research Day

ACOG District IV Meeting, Asheville, NC  
“Prevention of Venous Thromboembolism”  
“Stump the Professors: Panel”

American College of Surgeons’ Annual Meeting, Chicago, IL  
“Complicated Hysterectomy”

Visiting Professor: Hartford Hospital, Hartford CT

Visiting Professor: University of Connecticut, Farmington, CT

Visiting Professor: Memorial Sloan Kettering Cancer Center

Southern Obstetric and Gynecologic Seminar, Asheville, NC  
“Prevention of VTE following Gynecologic Surgery”  
“The Operative Note: What to say?”

Woman’s Hospital 7<sup>th</sup> Annual Founders Commemorative Lectureship, Woman’s Hospital,  
Baton Rouge, LA

**2008** Visiting Professor, Department of Obstetrics and Gynecology, Yale University

Course Director, ACOG CME Course “Complex Pelvic Surgery”, Phoenix, AZ

Invited Speaker: First Annual Gynecologic Cancer Symposium, Washington, DC April 18, 2008

Visiting Professor, University of Wisconsin Resident’s Research Day, Ben M. Peckman Memorial Lecturer, Madison, WI

ACOG representative to Symposium on Surveillance for Venous Thrombosis, American Society of Hematology, Washington DC

**2007** Visiting Professor, Department of Obstetrics and Gynecology, University of Miami

Faculty, University of Utah CME Course “Obstetrics and Gynecology: Update and Current Controversies” Park City Utah

Visiting Professor, Department of Obstetrics and Gynecology St. Louis University, St. Louis MO

Invited Lecturer: Marvin Camel Memorial Lecture, Washington University, Department of Obstetrics and Gynecology, St Louis, MO

Presidential Panel Speaker: Society of Pelvic Surgeons Annual Meeting, Cleveland, OH “What Can We do to prevent Venous Thromboembolism?”

**2006** Course Director: ACOG Annual Clinical Meeting: “Complex Gynecologic Surgery, Washington DC

Invited Speaker, ACOG District IV Annual Meeting, Palm Beach, FL

**2005** Course Director: ACOG Annual Clinical Meeting: “Complex Gynecologic Surgery, San Francisco

Course Director: ACOG Free-standing CME Course “Complex Gynecologic Surgery, Preventing Complications” Dana Point, CA

**2004** Society of Surgical Oncology: Symposium on Prevention of Venous Thromboembolism in the Surgical Oncology Patient

Postgraduate Course Faculty: ACOG Cancun, Mexico “Advanced Gynecologic Surgery”

American College of Obstetricians and Gynecologists, Annual Clinical Meeting, Philadelphia, PA  
Faculty, 120 Course: Special Topics for the Advanced Gynecologic Surgeon  
Faculty, Luncheon Seminar: “Prevention of Postoperative Venous Thromboembolism”  
Speaker: “Late-breaking News in Gynecologic Oncology”

Visiting Professor, University of Kansas School of Medicine, Truman Medical Center

Faculty: ACOG Indiana Section Meeting, Indianapolis  
“Surgery in the Obese Patient”, “Surgical Instruments”

**2003** Faculty, The 3<sup>rd</sup> Annual Cancer Conference, Aultman Cancer Center, Canton Ohio “Prevention and Management of Perioperative Venous Thromboembolism in the Gynecologic Cancer Patient”

Visiting Professor, Department of Obstetrics and Gynecology, University of Massachusetts, Worcester, MA



- 2002** Visiting Professor  
Bowman Gray School of Medicine
- Residents' Day Research Judge  
Winston Salem, NC
- American College of Surgeons' Annual Clinical Congress  
Panel Discussant: "Surgical Problems: Unexpected adnexal mass, tuboovarian abscess"  
Video Presentation: "Intraoperative Radiation Therapy for the treatment of Recurrent Cervical Carcinoma"  
Discussant: Video Presentation "Laparoscopic Infrarenal paraaortic lymphadenectomy"
- 2001** ACOG Annual Meeting  
Postgraduate Seminar  
Gynecologic Surgery in the Elderly
- George Washington University  
Medical Oncology Board Review Course (Faculty)
- 2000** Keynote Speaker  
Knoxville Obstetrical and Gynecological Society
- ACOG Annual Meeting (Course Director)  
Postgraduate Course  
Gynecologic Surgery for the Advanced Pelvic Surgeon
- Visiting Professor  
East Carolina University School of Medicine
- Visiting Professor  
Pennsylvania State University School of Medicine (Hershey)
- George Washington University  
Medical Oncology Board Review Course (Faculty)
- 1999** ACOG Annual Meeting (Course Director)  
Postgraduate Course  
Gynecologic Surgery for the Advanced Pelvic Surgeon
- George Washington University School of Medicine  
Medical Oncology Board Review Course (Faculty)
- Visiting Professor  
University of Virginia Health Sciences Center
- ACOG Annual Meeting (Course Director)  
Postgraduate Course  
Gynecologic Surgery for the Advanced Pelvic Surgeon
- 1998** ACOG Annual Meeting (Course Director)  
Postgraduate Course  
Gynecologic Surgery for the Advanced Pelvic Surgeon

George Washington University School of Medicine  
Medical Oncology Board Review Course (Faculty)

Visiting Professor  
Temple University School of Medicine

Keynote Speaker  
Maryland Obstetrical and Gynecological Society

Visiting Professor  
University of Louisville  
“Prevention of Postoperative Venous Thromboembolism”  
“Management of Patients with Thrombophilias”

**1997** Visiting Professor  
University of Utah, Salt Lake City

ACOG Annual Meeting (Course Director)  
Postgraduate Course  
Advanced Surgery for the Gynecologist

Visiting Professor  
Cleveland Clinic Foundation  
Department of Obstetrics and Gynecology  
Cleveland, Ohio

George Washington University School of Medicine  
Medical Oncology Board Review Course (Faculty)

Keynote Speaker  
Chicago Gynecological Society

Visiting Professor  
University of Louisville School of Medicine

Visiting Professor  
Washington University School of Medicine

Visiting Professor  
Johns Hopkins University School of Medicine

ACOG Annual Clinical Meeting  
Faculty, 120 Course: Special Topics for the Advanced Gynecologic Surgeon  
Faculty, Seminar: “Gynecologic Surgery in the Elderly”  
Faculty, Luncheon Seminar: “Prevention of Postoperative Venous Thromboembolism”

American College of Surgeons’ Annual Clinical Congress  
Panel Discussant: “Management of Gynecologic Problems Encountered by the General Surgeon at the time of Surgery. “Surgical Management of Ovarian Cancer Discovered at the time of Laparotomy”

**1996** Visiting Professor  
Dartmouth Medical School

Director ACOG Postgraduate Course  
Annual Clinical Meeting

Special Problems for the Advanced Gynecologic Surgeon

Visiting Professor  
University of Tennessee School of Medicine  
Chattanooga, Tennessee

Visiting Professor  
University of South Florida School of Medicine  
Tampa, Florida

Visiting Professor  
Washington University School of Medicine  
St. Louis, Missouri

John L. McKelvey Lecturer  
New Treatments for Ovarian Cancer  
University of Minnesota  
Minneapolis, Minnesota

Faculty - Taubman Ovarian Cancer Symposium  
St. Joseph's Hospital  
Tulsa, Oklahoma

ACOG Postgraduate Course (Course Director)  
San Juan, Puerto Rico  
Advanced Pelvic Surgery

**1994** ACOG Clinical Meeting CME Course  
Orlando, FL  
"Gynecologic Cancer"

Guest Speaker  
Seattle Gynecological Society Assembly

**1993** Visiting Professor - Department of OB/GYN  
University of Massachusetts  
Worcester, Massachusetts

ACOG Clinical Meeting - CME Course  
Washington, DC  
"Gynecologic Surgery"

PostGraduate Course in Obstetrics and Gynecology  
Kaiser-Permanente - Maui, Hawaii  
"Screening for Ovarian Cancer"  
"Management of CIN with LEEP"  
"Difficult Vaginal Hysterectomy"  
"Incisions and Wound Closures"

Duke/US Surgical Course  
"Laparoscopic Assisted Difficult Hysterectomy"

Visiting Professor - Mt. Sinai Hospital  
Baltimore, MD  
"Prevention of Thromboembolism"  
"Management of Ovarian Cancer"

- 1992** Visiting Professor - Department of OB/GYN  
University of Massachusetts  
Worcester, Massachusetts
- 1991** Visiting Professor  
George Washington University School of Medicine
- Course Director - ACOG Course (120 series)  
Annual Clinical Meeting  
New Orleans, Louisiana  
"Gynecologic Oncology for the Practicing Gynecologist"
- Course Director - ACOG Course  
Vancouver, British Columbia, Canada  
"Gynecologic Surgery"
- Visiting Professor  
Florida Hospital Cancer Center  
Orlando, Florida
- Paper Presentation  
Poster Presentation  
Society of Gynecologic Oncologists  
Orlando, Florida
- Visiting Professor  
Ohio State University School of Medicine  
Columbus, Ohio
- Medical Oncology Board Review Course  
George Washington University  
Washington, DC  
"Cervical, Vulvar and Vaginal Cancer"  
"Gestational Trophoblastic Disease"
- 1990** Society of Gynecologic Oncologists  
Breakfast Seminar  
"Diagnosis and Prevention of Postoperative Venous Thrombosis"
- Course Director - ACOG Course (120 Series)  
Annual Clinical Meeting  
San Francisco, California  
"Update in Clinical Gynecologic Oncology"
- Seminar, ACOG Clinical Meeting  
"Prevention of Postoperative Venous Thrombosis"
- 1989** Tumor Conference, Moore Regional Hospital  
Pinehurst, North Carolina
- Course Director - ACOG Course (120 Series) Annual Clinical Meeting, Atlanta, Georgia  
"Update in Clinical Gynecologic Oncology"
- Seminar, ACOG Clinical Meeting  
"Management of Early Ovarian Cancer"

Luncheon Conference, ACOG Annual Meeting  
"Reproductive Outcome Following Cancer Treatment"

Medical Oncology Board Review Course, George Washington University, Washington, DC  
"Cervical Cancer"

**1988** Matt Weiss Symposium  
St. Louis, Missouri

ACOG Annual Clinical Meeting  
Poster Session Presentation  
Review of Clinical Research Paper  
Review of Surgical Film  
Clinical Seminar Presentation

ACOG Course  
Juneau, Alaska  
"Gynecologic Surgery"

**1987** Update in Obstetrics and Gynecology  
Williamsburg, Virginia

North Carolina Obstetrical and Gynecological  
Society Meeting, Southern Pines, North Carolina

Visiting Professor, University of Minnesota School of Medicine, Minneapolis, Minnesota

ACOG Annual Clinical Meeting  
Clinical Paper Presentation  
Clinical Seminar Presentation

Southern Obstetrics and Gynecology Seminar  
Asheville, North Carolina

Satellite Teleconference  
Chicago, Illinois  
"Selected aspects of the care of the menopausal woman"

Chicago Medical Schools' Review Course  
Chicago, Illinois  
"Endometrial Carcinoma"

**Grants**

<b>Active Grants:</b>					
None at this time					
<b>Completed Grants:</b>					

Project Period	Agency	Title	Amount	Role	% of Effort
9/27/05-3/10/10	NIH/NICHD	Women's Reproductive Health Research (WRHR) Career Development Center at UNC - HDD050113-02	\$370,367 Annual Direct Costs	Principal Investigator	
3/1/00-3/31/02	Pharmacia Upjohn Pharmaceuticals	Randomized Comparison of Low Molecular Weight Heparin vs. Oral Anticoagulant Therapy for Long Term Anticoagulation in cancer patients – 98-Frag-069	\$ 73,000	Principal Investigator	
1/1/99-6/15/00	Zeneca Pharmaceuticals, Inc	Phase II/III Trial of IV ZD9331 in patients with recurrent refractory ovarian cancer	\$ 18,320	Principal Investigator	
6/1/98-6/1/00	Pharmacia Upjohn Pharmaceuticals	Prospective Randomized Trial Comparing Pneumatic Compression stockings To Low Molecular Weight Heparin (dalteparin) in the prevention of postoperative venous Thrombosis	\$ 100,760	Principal Investigator	
06/01/95 - 05/31/2000	National Cancer Institute	Hyperthermia and Perfusion Effects in Cancer Therapy	\$10,930,969	Investigator	2%
03/15/98-03/14/00	Novartis Pharmaceuticals	PSC 833 with taxol and carboplatin vs. carboplatin alone in patients with stage III ovarian cancer	\$ 102,240	Principal Investigator	
8/1/97-7/31/99	NIH	Hyperthermia and Perfusion Effects in Cancer Therapy	\$ 1,832,501	Co-Investigator	
5/28/97-12/31/98	Smithkline Beecham Pharmaceuticals	Oral Topotecan Single Agent for 5 days in patients with ovarian cancer	\$ 81,600	Principal Investigator	
01/01/93-12/31/98	National Cancer Institute	Comprehensive Cancer Center Core Support Grant	\$ 4,442,597	Program Director	10%
06/01/94 -	National Cancer	Autologous Bone	\$641,613	Investigator	10%

03/31/97	Institute	Marrow Transplantation in Breast and Ovarian Cancer: Project IB			
03/15/96-05/30/96	Ethicon, Inc	An Open, Controlled, Rand, Multicenter, Evaluation of Dyed Monocryl (Poliglecaprone 25) Synthetic Absorbable Suture as Compared to Surgical Gut (Chromic) Absorbable Suture	\$ 4,000	Principal Investigator	
1987-1996	American Cancer Society	Clinical Oncology Fellowship	\$ 20,000 (Direct)	Principal Investigator	5%
10/01/92-09/30/94	Centocor, Inc.	CA125 Post-Market Evaluation	\$ 8,750	Principal Investigator	5%
12/15/93-09/21/94	Smith-Kline Beecham Pharmaceutical	Phase III Topotecan versus Taxol in Women with Advanced Ovarian Carcinoma	\$ 37,500	Principal Investigator	5%
12/15/93-08/14/94	Smith-Kline Beecham Pharmaceutical	II Topotecan, Given as Five Daily Doses Every 21 Days in Ovarian Cancer	\$ 37,500	Principal Investigator	10%
07/01/89 - 03/31/94	Gynecologic Oncology Group	Gynecologic Oncology Group, Duke University Medical Center	\$ Contingent on number of patients	Co-Principal Investigator	30%
01/01/91 – 09/01/93	Organon, Inc.	ORG 2766 as a Neuroprotector from Cisplatin Chemotherapy for Ovarian Cancer	\$97, 575	Principal Investigator	10%
02/01/91 - 01/31/92	Organon, Inc.	Decapeptyl Treatment of Advanced Ovarian Cancer (Phase II Trial)	\$100,098	Principal Investigator	10%
11/01/90-10/31/91	Cytogen, Inc.	111In-CYT-103 Oncoprobe Evaluation of Ovarian Cancer	\$ 124,000	Principal Investigator	10%
07/01/86-06/30/91	National Institutes of Health	Avoidable Mortality from Cancers in Black Populations	\$ 4,647,291	Co-Investigator	10%
06/01/87 - 05/31/89	Public Health Service	Improved Instrumentation for the Diagnosis of Venous Thrombosis	\$162,804 (Direct)	Co-Principal Investigator	10%
05/01/88 -	National Cancer	Gynecologic	\$97,073	Co-Principal	10%



04/30/89	Institute	Oncology Group, Duke University Medical Center	(Direct)	Investigator	
01/01/88 - 12/30/88	Centocor, Inc.	Evaluation of the Safety and Preliminary Diagnostic Accuracy of IV Administered Indium-111-labeled OC-125 Monoclonal Antibody in Patients with Carcinoma of the Ovary	\$ 20,000 (Direct)	Co-Principal Investigator	5%
01/01/88 - 12/30/88	Centocor, Inc.	Evaluation of the Safety and Preliminary Diagnostic Accuracy of IV Administered Indium-111-labeled OV-TL3 Monoclonal Antibody in Patients with Carcinoma of the Ovary	\$ 40,000 (Direct)	Co-Principal Investigator	5%
05/01/85- 04/30/87	National Cancer Institute	Illinois Cancer Council - Gynecologic Oncology Group	\$ 21,000 (Direct)	Co-Principal Investigator	10%
07/01/81- 06/30/84	American Cancer Society	Junior Faculty Clinical Fellowship	\$ 35,000	Principal Investigator	30%
01/01/83- 12/31/83	Trent Foundation	In-vitro chemotherapy sensitivity testing of ovarian carcinoma	\$ 1,000	Principal Investigator	5%

### **PROFESSIONAL SERVICE**

#### **To discipline:**

##### **A. National/International**

**2023** President Elect, Society of Pelvic Surgeons

2021- 2022 Chair, NRG Oncology Data Monitoring Committee (Gynecologic Oncology Group)

2019-2023 Vice President, Society of Pelvic Surgeons  
Editorial board member: Journal of Gynecologic Surgery

2018-2020 Chair, Council of University Chairs of Obstetrics and Gynecology

- 2014** Chair, External Site Visit Committee, Department of Obstetrics and Gynecology, Penn State  
2014 University College of Medicine, Department of Obstetrics and Gynecology Member,  
2014 CUCOG Executive Board
- 2011** Member, American College of Surgeons Advisory Committee (ObGyn)  
2011 Member, CUCOG Executive Committee  
2011 Chair, ACOG Committee on Gynecologic Practice  
2011 Chair, SGO Nominating Committee
- 2010-2013** Immediate Past President, SGO  
2010-2013 Member, ACOG Executive Board (Representing the Society of Gynecologic Oncology)  
2011-2013 Chair, Committee on Gynecologic Practice, ACOG  
2007 -2010 Member, Education/Research Committee, Society of Pelvic Surgeons  
1988- 2005 Board Examiner: Obstetrics and Gynecology , ABOG  
2010-2011 Vice-Chair, Committee on Gynecologic Practice, ACOG  
2010 President, Society of Gynecologic Oncologists  
2009-2010 Editorial Board, Precis, Gynecology, ACOG  
Program Chair, Society of Pelvic Surgeons
- 2008**  
2008-2010 Committee on Gynecologic Practice, ACOG  
2008 President Elect II, Society of Gynecologic Oncologists  
2008 Chair, Membership Committee. Society of Pelvic Surgeons  
2007-2008 Vice President, Society of Gynecologic Oncologists
- 2007**  
2007 Editorial Board: Precis, Oncology, ACOG  
2007 SGO Executive Council, Society of Gynecologic Oncologists  
2007 Chair, Task Force to select Editor and Chief, Gynecologic Oncology, Society of Gynecologic Oncologists  
2007 Co-Chair, Strategic Planning Committee, Society of Gynecologic Oncologists  
2007 Member, By-laws Committee, Society of Gynecologic Oncologists
- 2005**  
2005 NC Breast and Cervical Cancer Control Program's (BCCCP) Medical Advisory Committee, North Carolina Department of Environment, Health, and Natural Resources  
2005-2019 Member, Clinical Cancer Committee, Moses Cone Health System  
2005-2019 Director, Gynecologic Oncology Program, Moses Cone Health System  
2005-2019 Member, Cancer Center Executive Committee, Moses Cone Health System  
1998-2005 Member, Executive Committee Cancer Center Clinical Service Unit, Duke University  
1998-2005 Co-Medical Director, Surgical Oncology Clinic, Duke University  
1992-2005 Member, Operating Room Committee, Duke University  
1991-2005 Principal Investigator, Duke University, Gynecologic Oncology Group  
1987-2005 Director of Gynecologic Oncology Fellowship Program (Duke Univ), ABOG  
1987-2005 Director, Gynecologic Oncology Program, Duke Comprehensive Cancer Center, Duke University  
1987-2005 Member, Steering Committee Strategic Planning Task Force, Duke Comprehensive Cancer Center, Duke University  
1987-2005 Member, Executive Committee, Duke Comprehensive Cancer Center, Duke University
- 2003**  
2003 Nominating Committee, Society of Gynecologic Oncologists  
2003 President and Program Chairman, Mid Atlantic Gynecologic Oncology Society

**2002**

- 2002 President-Elect, Mid Atlantic Gynecologic Oncology Society
- 2002 Member, Membership Committee, Society of Pelvic Surgeons
- 2002 Member, Oncology Strategic Planning Council, Duke University

**2001**

- 2001 Editorial Board: *Precis, Oncology*, ACOG
- 2001 Board Examiner: *Gynecologic Oncology*, ABOG

**2000**

- 2000 Member, Nominating Committee (AGOS Foundation)
- 2000 Program Chairman (Annual Meeting), Mid Atlantic Gynecologic Oncology Society
- 1994-2000 Member, Education Committee, Society of Gynecologic Oncologists

**1999**

- 1996-1999 Member, Fellowship Committee, AGOS

**1998**

- 1994-1998 Council Member, Society of Gynecologic Oncologists
- 1990-1998 Ovarian Cancer Committee, Gynecologic Oncology Group

**1997**

- 1993-1997 Editorial Board Member, Duke Cancer Report, Duke University
- 1993-1997 Committee on Gynecologic Practice, ACOG
- 1993-1997 Chairman, Committee on Gynecologic Oncology Practice, ACOG
- 1993-1997 ACOG Liaison Representative to the Society of Gynecologic Oncologists
- 1994-1997 Member, Committee on Clinical Practice, Society of Gynecologic Oncologists

**1995**

- 1994-1995 Chairman, 1995 Program Committee, Society of Gynecologic Oncologists

**1994**

- 1993-1994 Ad hoc Council Member, Society of Gynecologic Oncologists
- 1993-1994 Ad hoc Committee on Clinical Practice Policy Development Society of Gynecologic Oncologists
- 1994 Society of Pelvic Surgeons

**1993**

- 1991-1993 Chairman, Gynecology Committee, North Carolina OB/GYN Society
- 1991-1993 Member, Professional Activities Committee, North Carolina OB/GYN Society
- 1993 Medical Director, Duke North Hospital, 5900 Unit, Duke University
- 1993 Fellow, American Gynecological and Obstetrical Society
- 1993 Member, Ad hoc Committee to Define Criteria for Tenure in Clinical Medicine, Duke University
- 1993 Department of Surgery Chairman Search Committee, Duke University

**1992**

- 1990-1992 Member, Task Force on Cervical Cancer, Chairman, Subcommittee on Impact of Appropriate Follow-up Care, North Carolina Department of Environment, Health, and Natural Resources

**1991**

- 1987-1991 Co-Principal Investigator, Duke University Grant, Gynecologic Oncology Group
- 1987-1991 Committee on Technical Bulletins, ACOG
- 1991 Board Examiner: *Gynecologic Oncology*, ABOG
- 1991 Member, Director of Surgical Pathology Search Committee, Duke University

**1990**

- 1990 Member, Department of Pathology Chairman Search Committee, Duke University
- 1982-1990 Gynecologic Management Committee, Gynecologic Oncology Group

**1989**

- 1989 Fellow, American College of Surgeons

**1988**

- 1988 Mid-Atlantic Gynecologic Oncology Society
- 1988 Southern Obstetrical and Gynecological Seminar
- 1988 International Gynecologic Cancer Society
- 1988 Mid-Atlantic Gynecologic Oncology Society
- 1988 Southern Obstetrical and Gynecological Seminar

**1987**

- 1985-1987 Chicago Medical Society
- 1985-1987 Illinois Cancer Council
- 1985-1987 Illinois State Medical Society
- 1985-1987 Chicago Association of Gynecologic Oncologists
- 1987 North Carolina Medical Society
- 1987 North Carolina Obstetrical and Gynecological Society
- 1987 American Society of Clinical Oncologists

**1986**

- 1986 Chicago Gynecological Society

**1985**

- 1982-1985 Co-Principal Investigator, Duke University Grant, Gynecologic Oncology Group
- 1985 Central Association of Obstetricians and Gynecologists
- 1985 Central Association of Obstetricians and Gynecologists
- 1985 American Medical Association

**1982**

- 1982 Gynecologic Oncology Group
- 1982 Society of Gynecologic Oncologists
- 1982 Fellow, American College of Obstetricians and Gynecologists

**1979**

- 1979 Piedmont Obstetrical and Gynecological Society
- 1979 Bayard Carter Society of Obstetricians and Gynecologists
- 1979 Junior Fellow Section Chairman, ACOG

**1978**

- 1978 Junior Fellow Section Co-Chairman, ACOG

**1977**

- 1977 Junior Fellow Section Program Chairman, ACOG

**B. Within UNC-Chapel Hill**

- 2018-2021 Member, School of Medicine Promotions and Tenure Committee
- 2013-2019 Member, UNC Hospitals Committee of Perioperative Leaders
- 2011-2019 Member, Physicians and Associates Executive Committee
  - Member, P&A Finance and Compensation Committee
  - Member, P&A Committee on Payer Relations

2009- Member, Strategic Planning Committee: Hillsboro Hospital  
 2009-2019 Member, Strategic Planning Committee UNC HCS  
 2008-2019 Member, Dean's Advisory Committee on Part-Time Tenure Track Positions 2008-present Member Geographic Strategic Planning Committee  
 2008- 2019 Member UNC Strategic Planning Committee: Outpatient Surgery 2008-present Member UNC Strategic Planning Committee: Oncology  
 2007-2019 Member, Sheps Center Advisory Board  
 2007-2019 Member, Center for Women's Health Research Advisory Board  
 2007-2009 Team Leader (Attending Physicians' Experience) UNC Hospital Commitment to Caring 2006-present Medical Director, NC Women's Hospital Ambulatory Services  
 2005-2019 Dean's Advisory Committee  
 2005-2019 UNC Hospital Executive Committee  
 2005-2019 Physician and Chief, North Carolina Women's Hospital  
 2005-2019 Member, Physician and Associates Board/Faculty Physicians  
 2005-present Member, UNC Lineberger Cancer Center  
 2006, 2007 Chair, Data Safety Monitoring Board: An International Multi-Center Phase III Study of Chemoradiotherapy versus chemoradiotherapy plus hyperthermia for locally advanced cervical

### **Editorial Board Member**

1994-2004 Postgraduate Obstetrics and Gynecology  
 2003 Précis, Oncology, Second Edition  
 1995-2001 Associate Editor, Journal of Gynecologic Techniques  
 1994-2000 Gynecologic Oncology  
 2012-2015 Obstetrics and Gynecology  
 2020-present Journal of Gynecologic Surgery

### **Journal Reviewer**

Obstetrics and Gynecology

New England Journal of Medicine

American Journal of Obstetrics and Gynecology Journal of the American Medical Association (JAMA)

Annals of Internal Medicine

Pharmacotherapy

Fertility and Sterility

Gynecologic Oncology Cancer

International Journal of Gynecology and Obstetrics Journal of Pelvic Surgery

Journal of Gynecologic Surgery

# Exhibit B

Daniel Clarke-Pearson, M.D.  
Materials Considered

1. “A Survey of the Long-Term Effects of Talc and Kaolin Pleurodesis.” *British Journal of Diseases of the Chest* 73 (1979): 285–88.
2. Acencio, Milena M. P., Evaldo Marchi, Lisete R. Teixeira, Bruna Rocha Silva, Juliana Sanchez Silva, Carlos Sergio Rocha Silva, Vanessa Adelia Alvarenga, Leila Antonangelo, Francisco Suso Vargas, and Vera Luiza Capelozzi. “Talc Particles and Pleural Mesothelium Interface Modulate Apoptosis and Inflammation.” *Pathology* 46, no. S2 (2014): S76.
3. Acheson, E D, M J Gardner, E C Pippard, and L P Grime. “Mortality of Two Groups of Women Who Manufactured Gas Masks from Chrysotile and Crocidolite Asbestos: A 40-Year Follow-Up.” *British Journal of Industrial Medicine* 39, no. 4 (November 1982): 344–48.
4. ACOG. “Talc Use and Ovarian Cancer.” Statements, September 11, 2017.
5. Akhtar, Mohd Javed, Maqsood Ahamed, M.A. Majeed Khan, Salman A. Alrokayan, Iqbal Ahmad, and Sudhir Kumar. “Cytotoxicity and Apoptosis Induction by Nanoscale Talc Particles from Two Different Geographical Regions in Human Lung Epithelial Cells.” *Environmental Toxicology* 29 (2014): 394–406. <https://doi.org/10.1002/tox.21766>.
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7. American Cancer Society. “Talcum Powder and Cancer.” American Cancer Society, November 13, 2017.
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11. “ATSDR - Toxicological Profile: Asbestos.” Accessed August 16, 2018.
12. “ATSDR - Toxicological Profile: Silica.” Accessed August 16, 2018.
13. Baldwin, Lauren A., Bin Huang, Rachel W. Miller, Thomas Tucker, Scott T. Goodrich, Iwona Podzielinski, Christopher P. DeSimone, Fred R. Ueland, John R. van Nagell, and Leigh G. Seamon. “Ten-Year Relative Survival for Epithelial Ovarian Cancer:” *Obstetrics & Gynecology* 120, no. 3 (September 2012): 612–18.
14. Balkwill, Fran, and Alberto Mantovani. “Inflammation and Cancer: Back to Virchow?” *The Lancet* 357, no. 9255 (February 2001): 539–45. [https://doi.org/10.1016/S0140-6736\(00\)04046-0](https://doi.org/10.1016/S0140-6736(00)04046-0).
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16. Bartrip, P. W. J. “History of Asbestos Related Disease.” *Postgraduate Medical Journal* 80, no. 940 (February 1, 2004): 72–76. <https://doi.org/10.1136/pmj.2003.012526>.
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- Pulmonary Toxicity of Talc and Granite Dust as Estimated from an in Vivo Hamster Bioassay.” *Toxicology and Applied Pharmacology* 87, no. 2 (February 1987): 222–34.
18. Begg, Melissa D., and Dana March. “Cause and Association: Missing the Forest for the Trees.” *American Journal of Public Health* 108, no. 5 (May 2018): 620.
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Daniel Clarke-Pearson, M.D.

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33. Buz'Zard, Amber R., and Benjamin H. S. Lau. "Pycnogenol Reduces Talc-Induced Neoplastic Transformation in Human Ovarian Cell Cultures." *Phytotherapy Research: PTR* 21, no. 6 (June 2007): 579–86. <https://doi.org/10.1002/ptr.2117>.
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41. Chen, F., K. Gaitskell, M. J. Garcia, A. Albukhari, J. Tsaltas, and A. A. Ahmed. "Serous Tubal Intraepithelial Carcinomas Associated with High-Grade Serous Ovarian Carcinomas: A Systematic Review." *BJOG: An International Journal of Obstetrics and Gynaecology* 124, no. 6 (May 2017): 872–78.
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3. IMERYS048311
4. IMERYS051370
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8. IMERYS094601
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10. IMERYS105215
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16. IMERYS241866
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47. JNJ000026987  
48. JNJ000030027  
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55. JNJ000065601  
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62. JNJ000236810  
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70. JNJ000251888  
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77. JNJ000265536  
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81. JNJ000314406  
82. JNJ000347962  
83. JNJ000348778  
84. JNJ000381995  
85. JNJ000404860  
86. JNJ000460665  
87. JNJ000521616  
88. JNJ000526750  
89. JNJ000025132  
90. JNJ000046293  
91. JNJ000260700  
92. JNJAZ55\_000000577

Daniel Clarke-Pearson, M.D.

Materials Considered

93. JNJAZ55\_000000905
94. JNJAZ55\_000004563
95. JNJAZ55\_000006341
96. JNJAZ55\_000008177
97. JNJL61\_000014431
98. JNJMX68\_000003728
99. JNJMX68\_000012858
100. JNJMX68\_000013019
101. JNJMX68\_000013945
102. JNJMX68\_000017827
103. JNJNL61\_000079334
104. LUZ013094/P-26
105. P-321
106. P-47
107. PCPC\_MDL00062175
108. PCPC0075758
109. RJLEE-001497
110. WCD 002478 - Exhibit 32 Waldstreicher
  
111. Pltf\_MISC\_00000272 (JANSSEN-000001-19) 1962.
112. RA00461
113. RA00462
114. RA00469-70
115. RA00471-72
116. RA00473
117. RA00474
118. RA00475
119. RA00476
120. RA00477-78
121. JNJTALC001465273

### **Other Materials**

3<sup>rd</sup> Supplemental MDL Report of William Longo, PhD – Analysis of Non-Historical J&J’s Talcum Powder Consumer Product Containers and J&J Chinese Historical Talc Retain Samples, dated November 17, 2023.

William E. Longo, PhD – MDL Johnson’s Baby Powder Application and Exposure Container Calculations for Six Ovarian Cancer Victims Bellwether Cases, dated November 17, 2023.

Amended Expert Report of Shawn Levy, PhD, dated November 15, 2023.

**Case-Specific Depositions**

Deposition of Hilary Converse, dated 12/01/2020  
Deposition of Marquis Converse, dated 05/12/2021  
Deposition of Jessica Hughes, dated 05/12/2021  
Deposition of Peter Schwartz, M.D., dated 01/28/2021  
Deposition of Daniel Clarke-Pearson, M.D., dated 08/26/2021

**Plaintiff Profile Form**

Plaintiff Profile Form for Hilary Converse  
Amended Plaintiff Profile Form for Hilary Converse  
Second Amended Plaintiff Profile Form for Hilary Converse

**Medical Records (Defense)**

CONVERSE\_HILARY\_DREMILYFINE\_00001-00071  
CONVERSE\_HILARY\_DRPETERSCHWARTZ\_00001-00124  
HILARY\_DRPETERSCHWARTZ\_00125-00130  
CONVERSE\_HILARY\_SMILOWCANCERHOSPITAL\_00001-00232  
CONVERSE\_HILARY\_YALENEWHAVENHOSPITAL\_00001-02089  
ConverseH-ADPTCMR-00001-00022  
ConverseH-CNPCMR-00001-00031  
ConverseH-CVSCICO-00001-00005  
ConverseH-DDCCTMR-00001-00035  
ConverseH-DDCCTMR-00036-00038  
ConverseH-FineE-00001-00070  
ConverseH-FineE-00071-00196  
ConverseH-GFPCO-00001-00008  
ConverseH-GHSCMR-00001-00016  
ConverseH-GHSCMR-00017-00033  
ConverseH-GWICMR-00001-00003  
ConverseH-HHIMR-00001  
ConverseH-HHIMR-00002  
ConverseH-HHIMR-00003-00010  
ConverseH-ISSMPCMR-00001-00251  
ConverseH-KHCCMR-00001-00139  
ConverseH-KoC-00001-00004  
ConverseH-LuiF-00001-00023  
ConverseH-MGLIMR-00001-00027  
ConverseH-MGLIMR-00028-00062  
ConverseH-MSKCCMR-00001-00040  
ConverseH-MSMR-00001-00111  
ConverseH-NadelmannJ-00001-00061  
ConverseH-NadelmannJ-00062-00091  
ConverseH-NOSSPCMR-00001-00011

ConverseH-NVRMR-00001-00009  
ConverseH-NVRMR-00010-00022  
ConverseH-OR-00001-00146  
ConverseH-PHPMR-00001-00534  
ConverseH-QDNICVA-00001-00004  
ConverseH-QDW-00001-00060  
ConverseH-RobertsK-00001-00025  
ConverseH-RSMMD-00001-00064  
ConverseH-SchwartzP-00001-00060  
ConverseH-SchwartzP-00061-00065  
ConverseH-SGMCRad-00001-00003  
ConverseH-SMHMR-00001-00073  
ConverseH-SMHRad-00001-00009  
ConverseH-SNEENTFPSGLLPMR-00001-00032  
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ConverseH-USPCMR-00050-00053  
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ConverseH-WHRad-00001-00002  
ConverseH-WHRad-00003-00004  
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ConverseH-YBCMR-00020-00065  
ConverseH-YCCMR-00001-00484  
ConverseH-YCCMR-00485-01642  
ConverseH-YCGCMR-00001-00017  
ConverseH-YMDMR-00001-00118  
ConverseH-YCGCMR-00018-00044  
ConverseH-YMDMR-00119-00141  
ConverseH-YMGMR-00001-00147  
ConverseH-YMOMR-00001-00492  
ConverseH-YMSOSCHMR-00001-00162  
ConverseH-YNHBCMR-00001-00144  
ConverseH-YNHBCMR-00145-00150  
ConverseH-YNHGOAMR-00001-00219  
ConverseH-YNHHCMR-00001-00122  
ConverseH-YNHHLMR-00001-00244  
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ConverseH-YNHHPath-00009-00014  
ConverseH-YNHHPath-00015-00020  
ConverseH-YSIMR-00006-00079  
ConverseH-YuehonLuiF-00001-00034  
ConverseH-YUGOCMR-00001-00181



HCONVERSE-PL-00001-00834

**Medical Billing (Defense)**

ConverseH-ColbergJ-00001-00006  
ConverseH-CPCO-00001-00003  
ConverseH-CPCO-00004-00005  
ConverseH-FineE-00197-00201  
ConverseH-GSAPB-00001-00002  
ConverseH-GWICPB-00001-00004  
ConverseH-HHIPB-00001-00005  
ConverseH-ISSMPCPB-00001-00038  
ConverseH-KHCLLCPB-00001-00004  
ConverseH-KHCLLCPB-00005-00013  
ConverseH-KHCLLCPB-00014-00034  
ConverseH-MGLIPB-00001-00008  
ConverseH-MSKCCPB-00001-00011  
ConverseH-NVRainPB-00001-00002  
ConverseH-NVRPB-00001-00002  
ConverseH-NVRPB-00003-00005  
ConverseH-NVRPB-00006-00010  
ConverseH-NVSCPB-00001-00007  
ConverseH-PHPPB-00001-00031  
ConverseH-QDW-00061-00067  
ConverseH-RSMMD-00065-00088  
ConverseH-SNEENTFPSGLLPB-00001-00007  
ConverseH-THNEPB-00001-00011  
ConverseH-THNEPB-00012-00013  
ConverseH-USPCPB-00001-00005  
ConverseH-USPCPB-00006  
ConverseH-USPCPB-00007-00011  
ConverseH-WHPB-00001-00008  
ConverseH-YDAPB-00001-00003  
ConverseH-YMSOSCHPB-00001-00022  
ConverseH-YNHHPB-00001-00022  
ConverseH-YPLPB-00001-00003  
ConverseH-YUSMPB-00001-00022

**Defense Medical Records (NRS)**

ConverseH-ADPTCPB-00001-00003  
ConverseH-CFGOMR-00001-00002  
ConverseH-CFGOMR-00003-00004  
ConverseH-CFGOMR-00005-00006  
ConverseH-CFGOMR-00007-00008  
ConverseH-CFGOPB-00001-00003

ConverseH-CLPMR-00001-00004  
ConverseH-CLPMR-00005  
ConverseH-GHSCRad-00001-00004  
ConverseH-GHSCRad-00005-00008  
ConverseH-GSAMR-00001-00002  
ConverseH-GSAPB-00003-00005  
ConverseH-HHPPath-00001-00003  
ConverseH-HHPB-00001-00006  
ConverseH-HHPB-00007-00011  
ConverseH-HHRad-00001-00004  
ConverseH-JRMMDPCPCMR-00001-00002  
ConverseH-LanninD-00001-00005  
ConverseH-LCBPB-00001-00005  
ConverseH-LigginsC-00001-00003  
ConverseH-LigginsDrCasandra-00001-00003  
ConverseH-MCMR-00001-00007  
ConverseH-MSKCCRad-00001-00003  
ConverseH-NOSSPCPB-00001-00002  
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ConverseH-OMCMR-00003-00004  
ConverseH-OMCMR-00005-00006  
ConverseH-PiserchiaS-00001  
ConverseH-PiserchiaS-00002-00005  
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ConverseH-THNEPath-00001-00005  
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ConverseH-WICPB-00001-00002  
ConverseH-WICPB-00003-00006  
ConverseH-WNMR-00001-00004  
ConverseH-WNMR-00021-00024  
ConverseH-WNMR-00025-00030  
ConverseH-YCCPath-00001  
ConverseH-YNHHPPath-00001-00004  
ConverseH-YNHHPPath-00005-00008  
ConverseH-YNHHRad-00001-00002  
ConverseH-YSIMR-00001-00005  
ConverseH-YSMDSMR-00001  
ConverseH-YSMDSPB-00001  
ConverseH-YUSOMPATH-00001-00003

**Medical Records (Plaintiff)**

CONVERSE\_HILARY\_DIGESTIVE\_CNTR\_00001-00034  
CONVERSE\_HILARY\_DR\_EMILY\_FINE\_00001-00071  
CONVERSE\_HILARY\_DR\_FELIX\_YUEHON\_LUI\_00001-00008  
CONVERSE\_HILARY\_DR\_KO\_0001-00010  
CONVERSE\_HILARY\_DR\_NADELMANN\_00001-00006  
CONVERSE\_HILARY\_DR\_ROBERTS\_00001-00018  
CONVERSE\_HILARY\_DR\_SCHWARTZ\_00001-00124  
CONVERSE\_HILARY\_DR\_SCHWARTZ\_00125-00278  
CONVERSE\_HILARY\_DR\_SCHWARTZ\_00279-00324  
CONVERSE\_HILARY\_GENETICSTESTING\_00001-00025  
CONVERSE\_HILARY\_GRIFFINHOSPITAL\_00001-00014  
CONVERSE\_HILARY\_MEM\_SLOAN\_KETTERING\_00001-00021  
CONVERSE\_HILARY\_NAUGATUCKRADIOLOGY\_00001-00008  
CONVERSE\_HILARY\_NEURO\_ORTHO\_SPINE\_00001-00010  
CONVERSE\_HILARY\_NEWHAVEN\_GYN\_MEDS\_00001-00086  
CONVERSE\_HILARY\_NOS\_SPECIALISTS\_00001-00010  
CONVERSE\_HILARY\_PROHEALTH\_PHYSICIANS\_00001-00834  
CONVERSE\_HILARY\_QUEST\_00001-00002  
CONVERSE\_HILARY\_S\_NEWENGLAND\_ENT\_00001-00028  
CONVERSE\_HILARY\_SMILOW\_CANCER\_HOSP\_00001-000718  
CONVERSE\_HILARY\_SMILOW\_CANCER\_HOSP\_00719-00950  
CONVERSE\_HILARY\_SMILOW\_CANCER\_HOSP\_00951-01839  
CONVERSE\_HILARY\_SPINE\_SPORTS\_MEDS\_00001-00296  
CONVERSE\_HILARY\_UROLOGYSPECIALISTS\_00001-00048  
CONVERSE\_HILARY\_WATERBURYIMAGING\_00001-00002  
CONVERSE\_HILARY\_WATERBURYNEUROLOGY\_00001-00013  
CONVERSE\_HILARY\_WHITNEYIMAGING\_00001-00013  
CONVERSE\_HILARY\_YALE\_NEWHAVENHEALTH\_00001-00087  
CONVERSE\_HILARY\_YALE\_NEWHAVENHEALTH\_00088-00463  
CONVERSE\_HILARY\_YALENEWHAVENHOSPITAL\_00001-02089  
CONVERSE\_HILARY\_MYRIADGENETICS\_0001-0023  
CONVERSE\_HILARY\_NAUGATUCKRADIOLOGY\_0009  
CONVERSE\_HILARY\_S\_NEWENGLAND\_ENT\_0029-0048  
CONVERSE\_HILARY\_SMILOW\_CANCER\_HOSP\_1840-1862  
CONVERSE\_HILARY\_SPINE\_SPORTS\_MEDS\_0297-0371  
CONVERSE\_HILARY\_YALE\_NEWHAVENHEALTH\_0464-0598  
CONVERSE\_HILARY\_YALENEWHAVENHOSPITAL\_2090-2200

**Medical Billing (Plaintiff)**

CONVERSE\_HILARY\_COSTCOPHARMACY\_00001  
CONVERSE\_HILARY\_CVSCAREMARK\_00001-00004  
CONVERSE\_HILARY\_NEWHAVEN\_GYN\_BILLS\_00001-00022

CONVERSE\_HILARY\_SMILOW\_CANCER\_HOSP\_BILLS\_00001-00022  
CONVERSE\_HILARY\_WATERBURYIMAGING\_00001-00002  
CONVERSE\_HILARY\_DR\_EMILY\_FINE\_BILLING\_0001-0026  
CONVERSE\_HILARY\_MYRIADGENETICS\_BILLING\_0001-0003  
CONVERSE\_HILARY\_SPINE\_SPORTS\_MEDS\_BILLING\_0001-0066  
CONVERSE\_HILARY\_WATERBURYHOSP\_BILLING\_0001-0012  
CONVERSE\_HILARY\_WOMANSHEALTHCT\_BILLING\_0001-0022

**Plaintiff's Records (NRS)**

CONVERSE\_HILARY\_QUEST\_NORECS\_00001-00002  
CONVERSE\_HILARY\_WATERBURYHOSP\_RECSPURGED\_00001  
CONVERSE\_HILARY\_WATERBURYORTHO\_NORECS\_00001  
CONVERSE\_HILARY\_WOMANSHEALTHCT\_NORECS\_00001-00002  
CONVERSE\_HILARY\_CSHHC\_NORECS\_0001-0002  
CONVERSE\_HILARY\_CSHHC\_NORECS\_0003-0004  
CONVERSE\_HILARY\_DR\_EMILY\_FINE\_00072  
CONVERSE\_HILARY\_GRIFFINHOSPITAL\_0015-0022  
CONVERSE\_HILARY\_MIDSTATERRADIOLOGYASSOC\_0014  
CONVERSE\_HILARY\_NEURO\_ORTHO\_SPINE\_00011

**Other Documents**

Expert Report of John Godleski, M.D., dated July 12, 2021.

# Exhibit C

**Daniel Clarke-Pearson, MD**  
**Medical Legal Testimony in last 5 years**

Date: January 7, 2019

Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability  
Litigation MDL No. 2738

March 27, 2020

Khan v. Karl Storz, Howard Jones, Noh Goodman, Valley Health System  
SUPERIOR COURT OF NEW JERSEY  
2 LAW DIVISION - ESSEX COUNTY

March 9, 2021

Case: Ruscitto v. Jones

Date: September 13, 2021 and September 14, 2021

Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability  
Litigation MDL No. 2738

Date: January 17, 2024 and March 8, 2024

Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability  
Litigation MDL No. 2738

Hourly Rate: \$900/hour



# **EXHIBIT 34**



**Barnes-Jewish Hospital**  
**Washington University Medical Center**  
**Lauren V. Ackerman Laboratory of Surgical Pathology**  
One Barnes-Jewish Hospital Plaza  
St. Louis, MO 63110

**SURGICAL PATHOLOGY REPORT**  
**FINAL**

Patient Name: **GALLARDO, ANNA M.**

Address: 8231 PARKSIDE DR  
SAINT LOUIS, MO 631051615

Gender: F  
DOB: [REDACTED] 1952 (Age: 60)

Service: GYN

Location: 0173

MRN: [REDACTED]

Hospital #: [REDACTED]

Patient Type: SDSA

Accession #: **S13-28714**

Taken: 7/25/2013

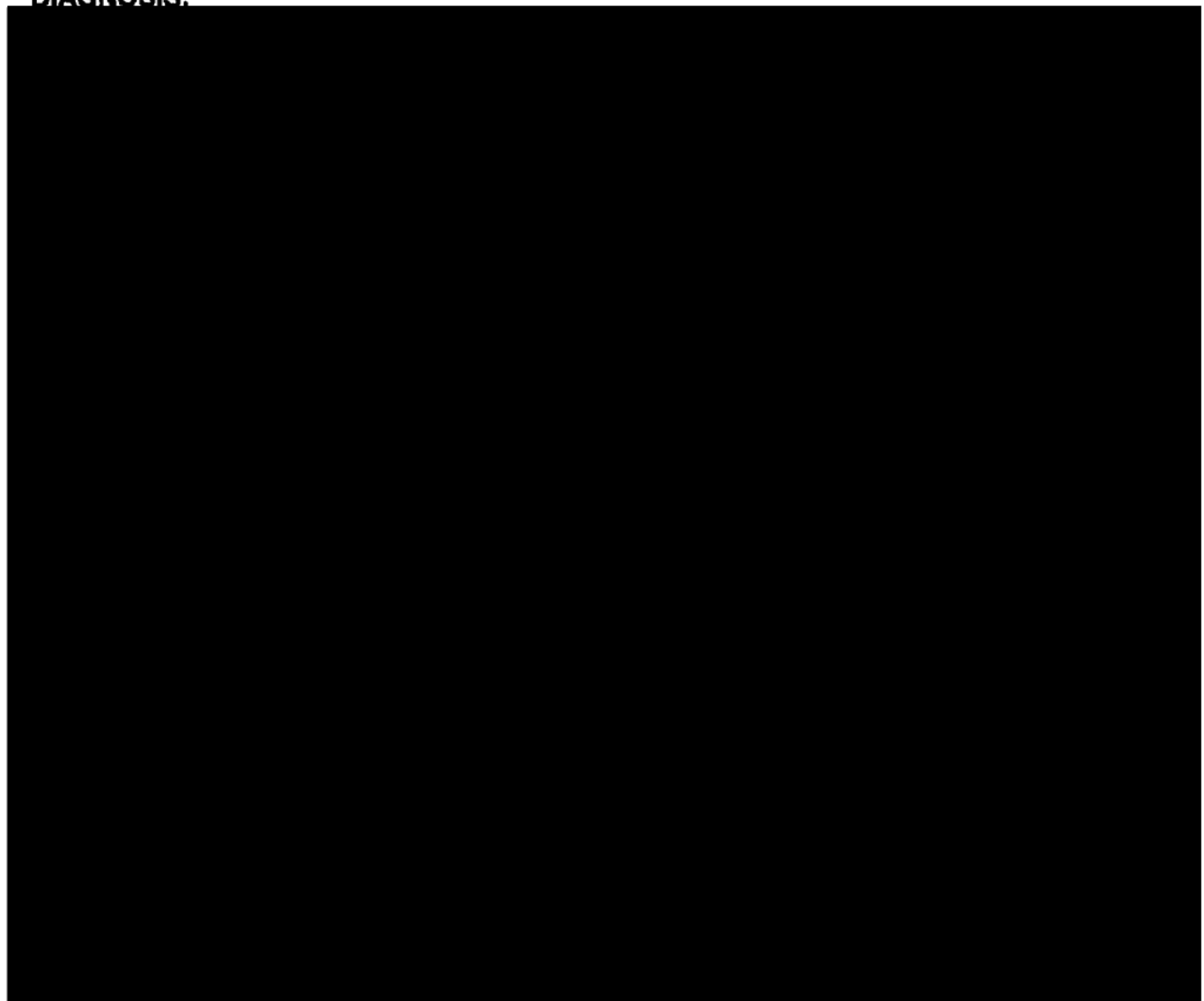
Received: 7/25/2013

Accessioned: 7/25/2013

Reported: 8/1/2013

Physician(s): Gary M. Wasserman, M.D.

**DIAGNOSIS:**





sdw/7/30/2013 19:49

By this signature, I attest that the above diagnosis is based upon my personal examination of the slides (and/or other material indicated in the diagnosis).

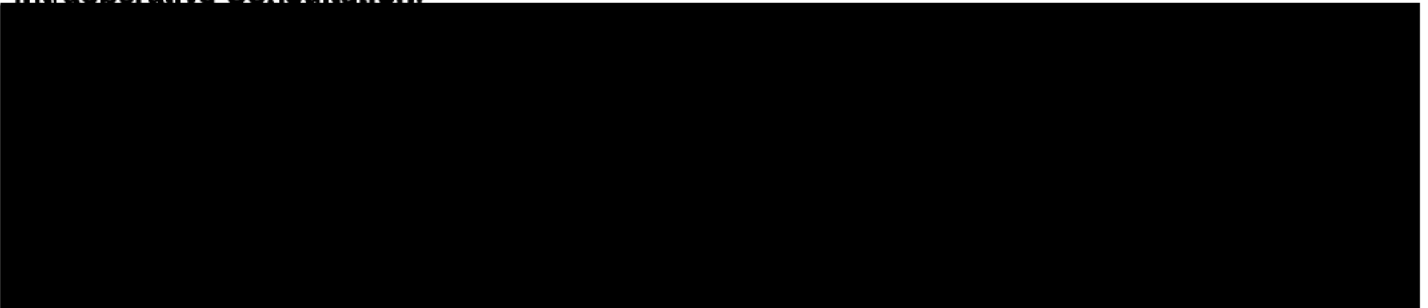
Horacio Maluf, M.D.

\*\*\*Report Electronically Reviewed and Signed Out By Horacio Maluf, M.D. 8/1/2013

19:48:40\*\*\*

---

**Intraoperative Consultation:**



Horacio Maluf, M.D.

**Microscopic Description and Comment:**

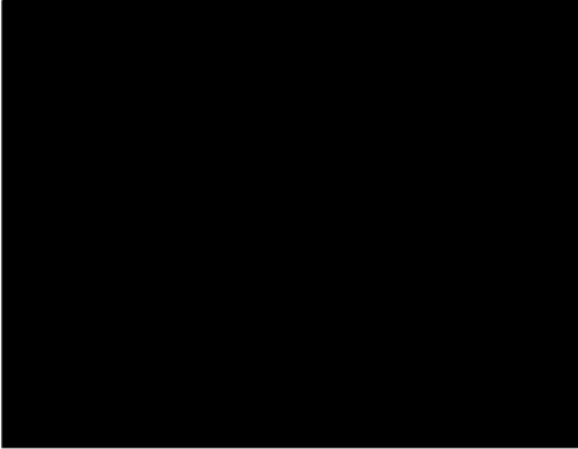


Reza Ataghehbandan, MD

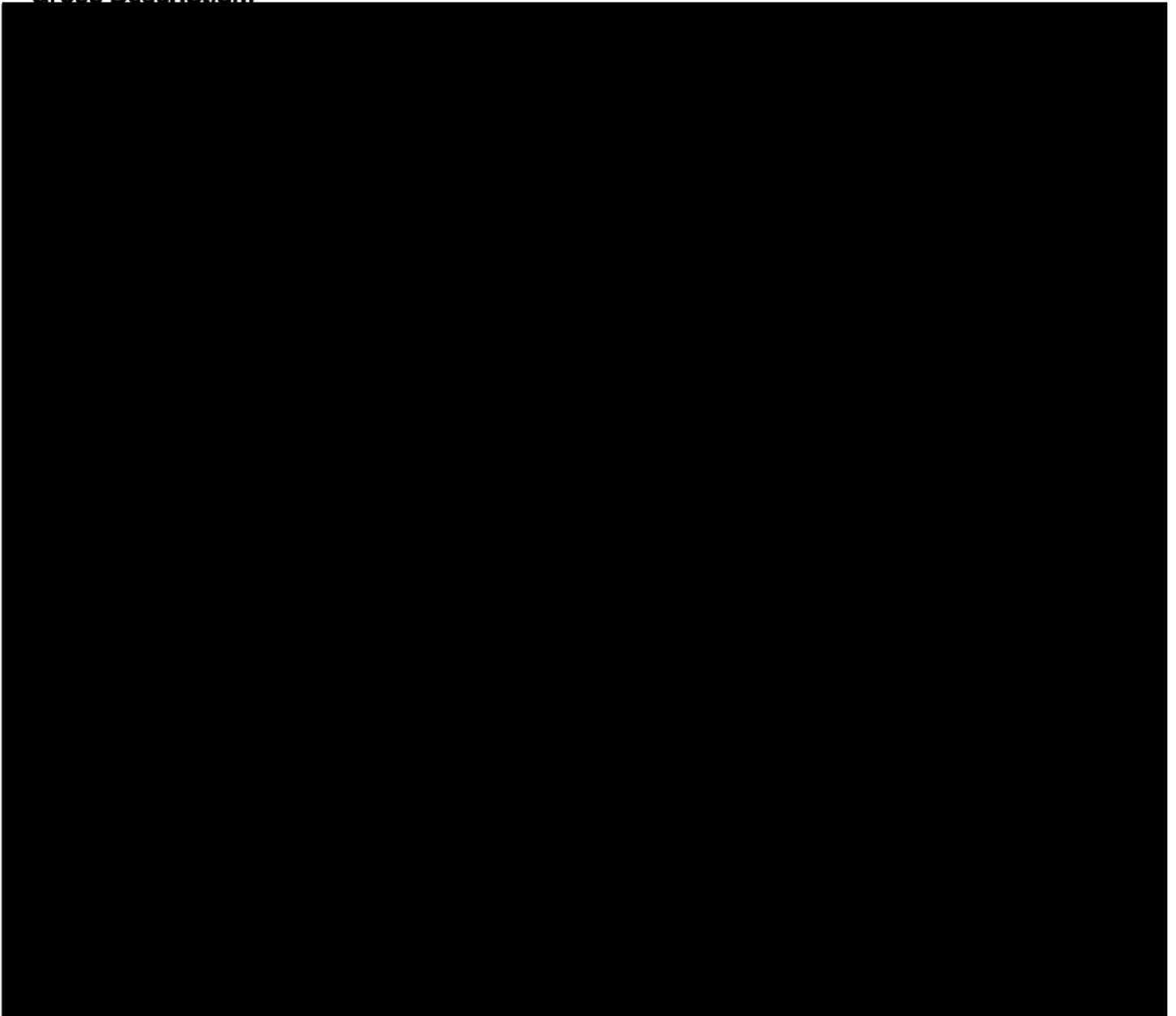
**History:**



**Specimen(s) Received:**



**Gross Description:**





**Barnes-Jewish Hospital**  
**Washington University Medical Center**  
**Lauren V. Ackerman Laboratory of Surgical Pathology**  
One Barnes-Jewish Hospital Plaza  
St. Louis, MO 63110  
(314) 362-0123

**CYTOPATHOLOGY REPORT**  
**FINAL**

Patient Name: **GALLARDO, ANNA M.**

Address: 8231 PARKSIDE D  
SAINT LOUIS, MO 631051615

Gender: F  
DOB: [REDACTED] 952 (Age: 60)

Service: GYN  
Location: 0173  
MRN: [REDACTED]  
Hospital #: [REDACTED]  
Patient Type: SDSA

Accession #: **M13-3243**  
Taken: 7/25/2013  
Received: 7/25/2013  
Accessioned: 7/25/2013  
Reported: 7/29/2013

Physician(s): Gary M. Wasserman, M.D.

**FINAL DIAGNOSIS**

btc/7/29/2013 15:48

By this signature, I attest that the above diagnosis is based upon my personal examination of the slides (and/or other material indicated in the diagnosis).

Brian Collins, M.D.

Margaux Guiney, CT(ASCP)\*\*\*Report Electronically Reviewed and Signed Out By Brian Collins, M.D. 7/29/2013 15:48:42\*\*\*

**Gross Description**

**Clinical Diagnosis and History**

**This Cytology report is available on-line on BLIS and Clinical Desktop.**

The performance characteristics of some immunohistochemical stains, in situ hybridization and fluorescent in situ hybridization tests and immunophenotyping by flow cytometry used in this report (if any) were determined by the Surgical Pathology Department at Barnes-Jewish Hospital as part of an ongoing quality assurance program and in compliance with broadly mandated regulations of the Clinical Laboratory Improvement Act of 1988 (CLIA '88). Some of these tests rely on the use of "in-house specific reagents" and are subject to specific labeling requirements by the US Food and Drug Administration. Such diagnostic tests may only be performed in a facility that is certified by the Department of Health and Human Services as a high complexity laboratory under CLIA '88. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Nevertheless, laboratory use of in-house specific reagents require that the following disclaimer be attached to the report.

This test was developed and its performance characteristics determined by the Surgical Pathology Department of Barnes-Jewish Hospital. It has not been cleared or approved by the U.S. Food and Drug Administration.



15/7/2013 17:30

Reza Alaghebandan, MD





## STAGE GROUPING

The pathologic stage assigned here should be regarded as provisional, and may change after integration of clinical data not provided with this specimen.

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### Surgical Pathology report is available on-line on BLIS and Clinical Desktop.

---

The performance characteristics of some immunohistochemical stains, fluorescence in situ hybridization tests and immunohistochemistry for time cytometry cited in this report (if any) were determined by the Surgical Pathology Department of Barnes-Jewish Hospital as part of an ongoing quality assurance program and in compliance with laboratory mandated regulations from the Clinical Laboratory Improvement Act of 1988 (CLIA '88). Some of these tests rely on the use of "analyte specific reagents" and are subject to specific labeling requirements by the US Food and Drug Administration. Such diagnostic tests may only be performed in a facility that is certified by the Department of Health and Human Services as a high complexity laboratory under CLIA '88. The FDA has determined that such evidence is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Nevertheless, based upon the medical use of analyte specific reagents require that the following disclaimer be attached to the report.

This test was developed and its performance characteristics determined by the Surgical Pathology Department of Barnes-Jewish Hospital. It has not been cleared or approved by the U.S. Food and Drug Administration.

# **EXHIBIT 35**

**PLAINTIFF PROFILE FORM**

This Plaintiff Profile Form (“PPF”) must be completed by the plaintiff or the representative of plaintiff’s decedent. In completing this PPF, you are under oath and must provide information that is true and complete to the best of your knowledge, information and belief after reasonable inquiry. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect.

In filling out this PPF, please use the following definitions: (1) “**health care provider**” means any hospital, clinic, medical center, physician’s office, infirmary, medical or diagnostic laboratory, or other facility that provides medical, dietary, psychiatric, or psychological care or advice, and any pharmacy, weight loss center, x-ray department, laboratory, physical therapist or physical therapy department, rehabilitation specialist, physician, psychiatrist, osteopath, homeopath, chiropractor, psychologist, nutritionist, dietician, or other persons or entities involved in the evaluation, diagnosis, care, and/or treatment of the plaintiff or plaintiff’s decedent; (2) “**document**” means any writing or record of every type that is in your possession, including but not limited to written documents, documents in electronic format, cassettes, videotapes, photographs, charts, computer discs or tapes, and x-rays, drawings, graphs, phone-records, non-identical copies, and other data compilations from which information can be obtained and translated, if necessary, by the respondent through electronic devices into reasonably usable form.

Information provided in this PPF will only be used for purposes related to this litigation and may be disclosed only as permitted by the protective order in this litigation. This PPF is completed pursuant to the Federal Rules of Civil Procedure governing discovery.

**1. CASE INFORMATION**

Name of Person Completing Form:	Anna	Gallardo
	First	M.I. Last
If you are completing this PPF in a representative capacity (e.g., on behalf of the estate of a deceased person), please complete the following:		
Your Name:		
	First	M.I. Last
Your relationship to individual you represent:		

**THE REST OF THIS PLAINTIFF PROFILE FORM REQUESTS INFORMATION ABOUT THE PERSON WHO USED JOHNSON'S BABY POWDER AND/OR SHOWER TO SHOWER AND WAS DIAGNOSED WITH OVARIAN CANCER**

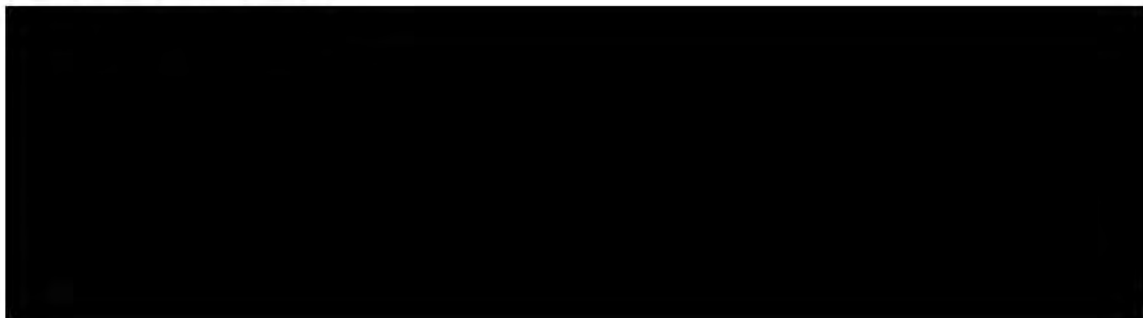
**2. PERSONAL INFORMATION**

Name:	Anna	Gallardo
	First	M.I. Last
Maiden/Other Names Used:		
Current or Last Known Address:	[REDACTED] Clayton MO 63105	
Date of Birth:	[REDACTED] 1952	Gender: Male: <input type="checkbox"/> Female: <input checked="" type="checkbox"/>
Date of Death (If Applicable):	<input checked="" type="checkbox"/> N/A	Social Security Number: [REDACTED]
Select Marriage Status:	Name of Spouse, if Married at time of filing Complaint:	
Married	Ramon Gallardo	

**3. TALCUM POWDER-RELATED CLAIM**

- a. Have you been diagnosed with one of the following types of cancer? b. If yes, please provide the approximate date of initial diagnosis (if more than one, for each initial diagnosis). c. If you were diagnosed with ovarian cancer, fallopian tube or primary peritoneal cancer, please provide the type. d. If you were diagnosed with ovarian cancer, fallopian tube or primary peritoneal cancer, please provide the stage.

<b>a. Type of Cancer</b>	<b>b. Date of Initial Diagnosis</b>	<b>c. Type of Ovarian, Fallopian tube, or Primary Peritoneal Cancer</b>	<b>d. Stage of Ovarian, Fallopian tube or Primary Peritoneal Cancer</b>
Ovarian	Jul 25 2013	Endometrioid	Stage II

**4. MEDICAL HISTORY:**

c. Have you ever been diagnosed with any of the following?

Condition	Yes/No/Unknown	Name and Address of Diagnosing Provider	Approximate Date of Diagnosis (if applicable)
BRCA1 or BRCA2 mutation			
Endometriosis			
Adenomyosis			
Irregular vaginal bleeding			
Ovarian Cysts			
Polycystic ovaries and/or Polycystic Ovarian Syndrome (PCOS)			
Uterine fibroids			
Infertility			
Breast cancer			
Lynch Syndrome			



Condition	Yes/No/Unknown	Name and Address of Diagnosing Provider	Approximate Date of Diagnosis (if applicable)
Other cancer (please specify below):			
N/A			
Obesity/overweight			
Pelvic Inflammatory Disease (PID)			
Colon Polyps			

6. Other than those injuries that you believe were caused by your use of body powder, do you currently suffer from any chronic illnesses or disabilities?

**FAMILY MEDICAL HISTORY**

7. Limiting this question to blood relatives, to the best of your knowledge, please indicate whether your *parents, siblings, children, grandparents, aunts, uncles, or first cousins* have ever suffered from or been treated for any type of cancer (including but not limited to ovarian cancer or breast cancer):

Relative's Name	Relation to you	Type of cancer	Date of cancer

8. Limiting this question to blood relatives, to the best of your knowledge, please indicate whether your *parents, siblings, children, grandparents, aunts, uncles, or first cousins* have ever been diagnosed with any genetic mutations, including but not limited to BRCA1 or BRCA2 mutations?

**HEALTH CARE PROVIDERS AND PHARMACIES**

9. Limiting your answer to primary care, gynecology and oncology healthcare providers, identify each doctor or other health care provider who you have seen for medical care and treatment from the ten (10) years prior to your ovarian cancer diagnosis to the present. In particular, please use your best efforts to list all of the primary care providers during this period.

Doctor or Healthcare Provider's Name	Doctor or Healthcare Provider's Specialty	Address	Approximate Years of Visits
			to
			to
			to
			to
			to
			to
			to

[illegible]

10. If any of your healthcare providers who you have seen in relation to treatment and care of **ovarian cancer or any other form of cancer** were not identified previously, please identify for each such provider:

[illegible]

11. Limiting your response to visits for issues related to cancer and to gynecologic issues other than pregnancy, identify each hospital, clinic, or health care facility where you were hospitalized (inpatient, out-patient, or emergency room visit) from the (10) years prior to your ovarian cancer diagnosis to the present:

Name	Address	Admission Date(s)	Reason for Admission Approx. Years of Visits



[illegible]

12. To the best of your recollection, identify each pharmacy that has regularly dispensed medication to you from the ten (10) years prior to your ovarian cancer diagnosis to the present:

Name of Pharmacy	Address of Pharmacy	Approx. Years You Used Pharmacy
		to
		to
		to
		to
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		to
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		to
		to

Name of Pharmacy	Address of Pharmacy	Approx. Years You Used Pharmacy
		to
		to
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		to

13. Has any health care provider told you the cause(s) of your ovarian cancer?



Healthcare Provider's Name	Approximate Date of Conversation	Substance of Conversation

14. Have you had any communications with your health care providers, orally or in writing, about whether your condition is related to your use of Johnson’s Baby Powder and/or Shower to Shower?



Healthcare Provider’s Name	Approximate Date of Conversation

**TALCUM POWDER PRODUCT USE**

16. Have you ever used Johnson's Baby Powder? Choose Yes/No: Yes

If yes, identify:

- a) Did you apply the product to your genital area? Choose Yes/No: Yes
- b) Approximate year of first use: 1968
- c) Approximate year of last use: 1988
- d) Frequency of use during these dates: Daily

17. Have you ever used Johnson & Johnson Shower to Shower? Choose Yes/No: No

If yes, identify:

- a) Did you apply the product to your genital area? Choose Yes/No:
- b) Approximate year of first use:
- c) Approximate year of last use:
- d) Frequency of use during these dates:

18. Have you ever used any other cosmetic powder product(s) in your genital area?

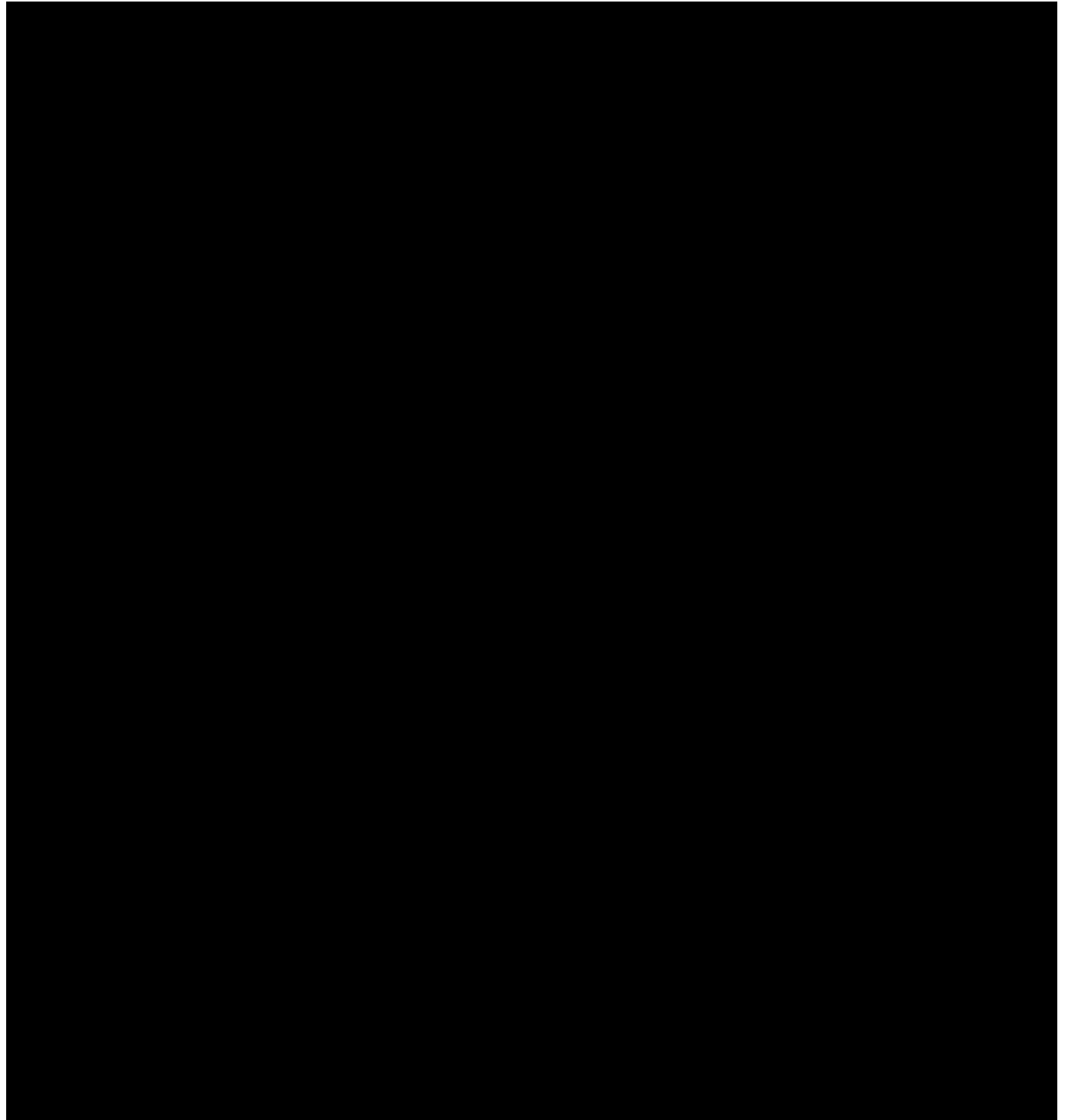
Choose Yes/No: No

If yes, identify:

- a) Name of product(s):
- b) Approximate year of first use:
- c) Approximate year of last use:
  
- a) Name of product(s):
- b) Approximate year of first use:
- c) Approximate year of last use:



**MEDICAL BACKGROUND OF BODY POWDER USER**



**24. Employment History:**

Are you currently employed? Choose Yes/No: <u>Yes</u>
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If yes, please identify your current employer and position:
---

Self-Employed
---------------

**25. Education:**

Highest Educational Degree	Educational Institution
High School Diploma	Laboure High School

**DOCUMENT DEMANDS**

Documents in your possession, including writings on paper or in electronic form (if you have any of the following materials in your custody or possession, please indicate which documents you have and attach a copy of them to this Plaintiff Profile Form):

1. All documents relating to plaintiff's purchase(s) or acquisition(s) of Johnson's Baby Powder or Shower to Shower, including but not limited to, store receipts, credit card receipts, containers, labels, or other records of purchase or acquisition.
2. All medical records, reports, and/or documents from any hospital, physician, or other health care provider who treated plaintiff for ovarian cancer or any gynecologic disease, condition or symptom alleged in the Complaint and/or PPF.
3. If applicable, decedent-user's death certificate and copies of letters testamentary or letters of administration confirming standing of the named plaintiff.
4. A copy of all pathology reports related to plaintiff's/decedent's diagnosis or recurrence of ovarian cancer.
5. A copy of all reports reflecting any genetic testing undertaken on plaintiff/decedent.

**DECLARATION**

I declare under penalty of perjury that all of the information provided in connection with this Short Form Plaintiff Profile Form is true and correct to the best of my knowledge, information, and belief formed after due diligence and reasonable inquiry. I acknowledge that I have an obligation to supplement the above responses if I become aware of additional responsive information, or if I learn that they are in some material respects incomplete or incorrect.

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature of Plaintiff\_\_\_\_\_  
Print Name of Signing Plaintiff

# **EXHIBIT 36**

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

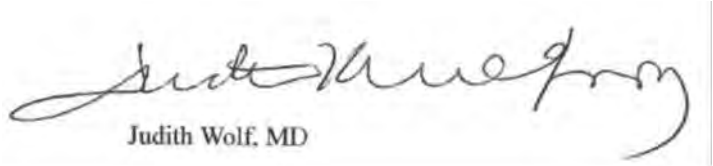
IN RE JOHNSON & JOHNSON  
TALCUM POWDER PRODUCTS  
MARKETING, SALES PRACTICES, AND  
PRODUCTS LIABILITY LITIGATION

MDL NO. 16-2738 (MAS) (RLS)

*THIS DOCUMENT RELATES TO:*  
*Gallardo v. Johnson & Johnson, et al.*  
*3:18-cv-10840*

SECOND AMENDED RULE 26 EXPERT  
REPORT OF JUDITH WOLF, MD

Date: May 28, 2024



Judith Wolf, MD

## **I. BIOGRAPHY AND QUALIFICATIONS**

I am a board certified gynecologic oncologist, a physician specializing in the care of women with cancer with more than thirty years experience. I attended medical school at Northeast Ohio Universities College of Medicine and then moved to Texas where I completed residency at the University of Texas San Antonio and fellowship at MD Anderson Cancer Center where I remained on faculty for more than twenty years as Professor in the Department of Gynecologic Oncology. My area of expertise is ovarian cancer - diagnosis, research, treatment, and patient advocacy.

I have authored or co-authored over 100 peer-reviewed research articles and was the principal investigator or co-investigator for eleven research grants related to gynecologic cancers. Additionally, I have served as the principal investigator, co-principal investigator, or collaborator on numerous protocols, and have presented at more than 50 conferences, as well as at numerous scientific exhibitions and seminars. The majority of these have dealt with some aspect of ovarian cancer.

My research began when I was a fellow in gynecologic oncology. In addition to two years of clinical training, I spent two years working in the lab and getting my master's degree in biomedical science from The University of Texas School of Biomedical Sciences in Houston. My research as a graduate student was in investigating targets for therapy in ovarian cancer. One of these led to a phase I Clinical trial for women with ovarian cancer using a targeted therapy. This trial was part of a larger National Cancer Institute (NCI) grant. After completing training, I maintained a research lab for over 10 years, investigating gene therapy for the treatment of both ovarian and cervical cancer. My laboratory research in ovarian cancer led to a Clinical trial of gene therapy for women with ovarian cancer. Being able to see the long road it takes to bring new therapies from the lab to clinic fostered my continued interest in clinical trials and led me to become involved in both investigator initiated and NCI cooperative group clinical trials - Phase II and III trials of new therapies for ovarian cancer.

Throughout my tenure as a Professor at MD Anderson Cancer Center, I was recruited to join the biomedical industry. It wasn't until 2014, when Vermillion, a diagnostic company, recruited me as a Chief Medical Officer that I felt compelled to make a change in my career path. By this point in time, I had cared for hundreds of women with ovarian cancer, and saw the devastation this disease causes, with little improvement in the overall prognosis in more than twenty years. Working with a diagnostic company, focused on the early detection of ovarian cancer, seemed to me to be another way I could work to make a difference. While at Vermillion, I co-authored several publications, helped the company gain FDA clearance for their second-generation multiprotein biomarker assay for ovarian cancer detection and was integral in the company obtaining a \$7.5 million dollar grant from the State of Texas for ovarian cancer detection.

After two years at Vermillion, I was recruited by another small start-up diagnostic company, ProvistaDx, as Chief Medical Officer. ProvistaDx was using similar multi-protein assays (like Vermillion) but combining them with antibodies to try to detect both breast and ovarian cancer early. While at ProvistaDx, we published several articles in the breast cancer detection area. This

effort included their first publication setting forth this combined technology for ovarian cancer detection.

Working in these diagnostic companies exposed me to some of the intricacies of working in the biomedical industry and research from the viewpoint of a publicly traded company (Vermillion) and a small private start-up (ProvistaDx). Additionally, I learned much about the regulation of the biomedical industry.

In mid-2018, I left my company position to have more time to focus on my volunteer and advocacy work for women's health with a large focus on ovarian cancer. In the mid-1990s, I became involved with raising awareness and educating women about ovarian cancer through my work with the National Ovarian Cancer Coalition (NOCC), serving as a medical board member and as a governing board member, a position I have held for more twenty years. NOCC's mission is to raise awareness and educate women and their families about ovarian cancer. Additionally, I combined my love of running and passion for ovarian cancer to organize a charity 5K walk/run to raise awareness and research money for the Blanton/Davis Ovarian Cancer Research Program at MD Anderson Cancer Center. This race has been going on now for more than twenty-five years and has raised millions of dollars for ovarian cancer research.

In 2014, I became a member of the board of the Society for Women's Health Research which is a national nonprofit dedicated to promoting research on biological differences in disease and improving women's health. Additionally, I began working with Health Volunteers Overseas. I have volunteered in Vietnam, Honduras and Haiti working with physicians in these countries to train them to be better able to care for women with gynecologic cancers. I have worked with HVO for the past year and a half and currently head a project that trains young surgeons in Nepal to care for women with ovarian, cervical and uterine cancers. Some of this work has been paused since early 2020 because of the COVID-19 pandemic.

I continue to practice medicine as a Gynecologic Oncologist, treating women with ovarian cancer and other gynecologic malignancies in numerous medical centers around the country. I am recruited on a regular basis to serve in communities which are lacking gynecologic oncology care.

## **II. METHODOLOGY**

I was asked to make a determination as to whether the genital use of talcum powder can cause ovarian cancer. I approached this issue in a similar way and with the same rigor that I would use in my professional practice, both clinically and in research. This is an exercise I have used regularly throughout my thirty plus year career. I reviewed extensive medical and scientific literature (including epidemiological, animal, mechanistic studies, and reviews on all relevant topics). I also researched publicly available information related to talcum powder products, their safety, and their association with ovarian cancer. Many of these sources were obtained through articles and references from my personal library of journals, textbooks, as well as PubMed searches on relevant topics. Additional relevant literature, documents, and testimony were provided by the attorneys working on this case. I also requested additional information on various relevant issues when appropriate.



In doing this research, I applied the same standards that I use in clinical medicine to consider the reliability and validity of the medical and scientific literature, assessing the evidence according to the strengths and weaknesses of the study under review. I considered an extensive body of relevant literature, without regard to the nature of the specific findings. I based the opinions provided in this report using a weight of the evidence methodology in the context of Bradford Hill concepts.

### III. OVERVIEW OF OVARIAN CANCER

Ovarian cancer is a group of malignancies that are believed to begin in ovarian or fallopian tube tissue. There are three groups of cancers based on the cell type from which they arise - germ cell, stromal, and epithelial cancers. Epithelial cancers (EOC) account for the vast majority of ovarian cancers (greater than 90%) and are further subdivided based on the microscopic characteristics of the cells. These subtypes include serous, endometrioid, clear cell, mucinous, undifferentiated or mixed. Of these, serous is by far the most common and accounts for 70% of EOC. Epithelial ovarian cancers are those that are associated with talcum powder products.

Epithelial carcinoma of the ovary, fallopian tube, and peritoneum are usually considered as a single entity due to their common clinical behavior, risk factors, and pathogenesis. Over the past decade, research has found that many serous carcinomas of the ovary may begin in the cells that line the distal portion of the fallopian tube. These cells then leak, drip, or “escape” from the tube and the ovary (which is next to the tube) or the peritoneum (the layer that lines the inside of the abdomen and pelvis). (Levanon 2008, Chen et al. 2017; Singh et al. 2016; Soong et al. 2018). Cancers that clinically appear to arise from the fallopian tube, ovary or peritoneum have the same microscopic appearance, pattern of spread (throughout the pelvis and abdomen), and response to treatment. This information is consistent with the role of talcum powder in cancer development.

Ovarian cancer is a relatively rare cancer. The American Cancer Society estimates in 2023, 19,710 new cases of ovarian cancer compared to 300,590 new cases of breast cancer.<sup>1</sup> There is no screening for ovarian cancer and symptoms are vague. This presentation leads to late diagnosis for more than 75% of patients. Because of these factors, ovarian cancer is the deadliest gynecologic malignancy in the U.S. Seventy to seventy-five percent of women with advanced stage EOC die from their disease, usually from bowel obstruction, following years of chemotherapy treatment.

The National Cancer Institute defines a risk factor as something that increases the chances of developing a disease. Associations can occur that are not actually linked with a disease. A causative risk factor is one that increases the chances of developing a disease by means of a known or predictable mechanism. In other words, it is more than a mere association. (Vineis 2017). As a physician, I use the terms risk factor and contributing cause interchangeably when the known or predictable mechanism for the effect is plausible.

The most significant risk factors associated with ovarian cancer are inherited susceptibility genes, primarily BRCA1, BRCA2, and the mismatch repair genes (associated with Lynch syndrome). BRCA mutations account for 75% of all hereditary ovarian cancers. A woman with BRCA1 gene

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<sup>1</sup> <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2023/2023-cancer-facts-and-figures.pdf>.

mutation has a 39-46% lifetime risk of developing ovarian cancer; a woman with BRCA2 gene mutation has an 11-27% lifetime risk of developing ovarian cancer. (Ring et al. 2017). It is estimated that these hereditary gene mutations account for 10-15% of all ovarian cancer and 75% of all hereditary ovarian cancers. (Lancaster et al. 2015). It is important to distinguish these inherited gene mutations from induced mutations caused by inflammation or environmental insults. Women with a genetic predisposition to developing ovarian cancer are still subject to other environmental and reproductive risk factors.

In addition to talc and asbestos exposure, other risk factors that have been linked to EOC include increasing age, nulliparity, infertility, endometriosis, obesity, polycystic ovarian syndrome, use of an intrauterine device, history of pelvic inflammatory disease, and cigarette smoking (for mucinous carcinoma). Protective factors (associated with a decreased risk of EOC) include previous pregnancy, history of breastfeeding, oral contraceptives, and tubal ligation. (Hunn and Rodriguez 2012; Wu 2015; IOM 2016; Mallen, Townsend, and Tworoger 2018; Park et al. 2018; Gentry-Maharaj et al. 2018; Lheureux et al. 2019). It is important to note that risk factors can interact with each other or act independently. They can act in a cumulative, additive, and/or synergistic fashion. (Wu et al. 2018; Vitonis et al. 2011; e.g., Phung et al. 2022). For example, Phung et al. (2022) examined the effect of well-established ovarian cancer risk factors in women with and without endometriosis. The pooled analysis of 9 case-controlled studies in the Ovarian Cancer Association Consortium demonstrated that there was a greater increased risk of ovarian cancer with genital talc use in women with endometriosis (OR 1.38, 95% CI 1.04-1.84) versus those without endometriosis (OR 1.12, 95% CI 1.01-1.25).

Because cancer is not caused by a single genetic abnormality, ovarian cancer development is multifactorial. For example, not everyone who has an inherited BRCA mutation develops ovarian cancer, and not everyone who gets ovarian cancer has an inherited BRCA mutation. This was recognized as early as 1971 when Knudson published his “two-hit” hypothesis of carcinogenesis. (Knudson 1971).

Talcum powder dusting is often referred to as a “lifestyle factor”. There are no medical benefits; any risk, particularly a risk of something as devastating and deadly as ovarian cancer, is unacceptable. Because of this, I advise all my patients not to use talcum powder products or to stop using them if they are already doing so.

Most women with EOC present with pelvic or abdominal pain, bloating, and/or gastrointestinal symptoms. Diagnosis is based upon pathologic evaluation of tissue. Knowledge and evaluation of the pathology of ovarian cancer is part of every gynecologic oncologist’s training and experience. Staging is surgical. In a patient with advanced stage ovarian cancer (stage 3 and 4), the cancer is spread throughout the abdomen and pelvis with typically thousands of tumor nodules covering the surface of all internal organs, along with several liters of fluid containing cancer cells (ascites).

Treatment for ovarian cancer is a combination of surgery and chemotherapy. Most women with advanced disease obtain 1-2 years of remission after treatment, and then their cancer recurs. Once ovarian cancer recurs, it is not curable, and most patients spend the remainder of their life on chemotherapy in an attempt to extend their life spans and minimize their often severe symptoms.

#### **IV. HISTORICAL BACKGROUND OF TALC**

Johnson & Johnson's baby powder was introduced to consumers in 1894. (Gurowitz 2007).

In the late 1940s and early 1950s, there were numerous articles (including at least one from Johnson & Johnson's own lab) describing the inflammatory properties of talc when introduced into the peritoneal cavity experimentally or through surgical gloves and the relative safety of starch products in the same setting. (Eberl and George 1948; Graham and Jenkins 1952). In 1953, Johnson & Johnson submitted a patent application for a "non-irritating" starch-based dusting powder due to the severe postoperative complications and strong inflammatory reaction frequently caused by talc. (Caldwell et al. 1953). In 1967, the association between asbestos and ovarian cancer was reported (J. Graham and Graham 1967).

Henderson first identified talc particles deep in ovarian tissue in 1971. (Henderson et al. 1971). Dr. Woodruff and colleagues at Johns Hopkins began raising awareness regarding environmental toxins like talc as etiologic factors in the pathogenesis of ovarian cancer in the early 1970s. (Parmley and Woodruff 1974).

In 1979, Longo and Young cautioned the cosmetic industry regarding the dangers of talc in *The Lancet*: "Epidemiological, experimental, and clinical data seem to link asbestos and talc with ovarian cancer. Direct passage of talc or asbestos-contaminated talc through the female reproductive tract to the ovarian surface may play an aetiological role. Further systematic evaluation of talc and asbestos as ovarian carcinogens is needed. What is disturbing is that a consultant to the cosmetic industry feels that further research on the biological effects of talc 'merits little priority.'" (D. L. Longo and Young 1979). The first epidemiologic study on the association between talc and ovarian cancer was published in 1982. (Cramer et al. 1982).

Between 1992 and 1995, concerns were raised in the medical literature regarding risks, including ovarian cancer, of talc on condoms. (e.g., Kang, Griffin, and Ellis 1992; Kasper and Chandler 1995). In 1995, the condom industry voluntarily agreed to stop dusting condoms with talc due to ovarian cancer concerns. ("PCPC\_MDL00062175" 1999; McCullough 1996). Recommendations regarding the use of talcum powder on diaphragms were also discontinued in the late 1990s. In 1998, Janssen, a subsidiary of Johnson & Johnson, changed the warning on its All-Flex Diaphragm to state "Powders should not be used with the diaphragm."<sup>2</sup> Although the inflammatory properties of powder from surgical gloves were known for decades, the FDA only banned its use in 2016. (Federal Register / Vol. 81, No. 243).

#### **V. EPIDEMIOLOGY**

Since the early 1980's, there have been numerous epidemiological studies evaluating the risk of ovarian cancer with talcum powder usage. To the present time, there are over 25 case-control studies, three prospective cohort studies, two pooled analyses, and ten meta-analyses. I assessed all of these studies.

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<sup>2</sup> Janssen sold the Ortho diaphragms beginning in the 1960s. The 1962 instructions stated, "Dust diaphragm when dry with talcum powder and return it to the original container." ("Pltf\_MISC\_00000272 (JANSSEN-000001-19)" 1962).

A case-control study is designed to help determine if an exposure is associated with an outcome, in this case ovarian cancer. First, researchers identify women with and without ovarian cancer - cases and controls. Then they look back in time to learn which subjects in each group had talcum powder exposure(s), comparing the frequency of the exposure in the case group to the control group.

A case-control study is always retrospective because it starts with an outcome then traces it back to investigate exposures. Advantages of case-control studies are that they are comparatively efficient, less expensive, and easier to perform. Potential weaknesses include selection bias, (because they are not randomized) and recall bias. Case-control studies are particularly appropriate for uncommon diseases, like ovarian cancer, in which a very large cohort would be required to accumulate enough cases for analysis. (Narod 2016).

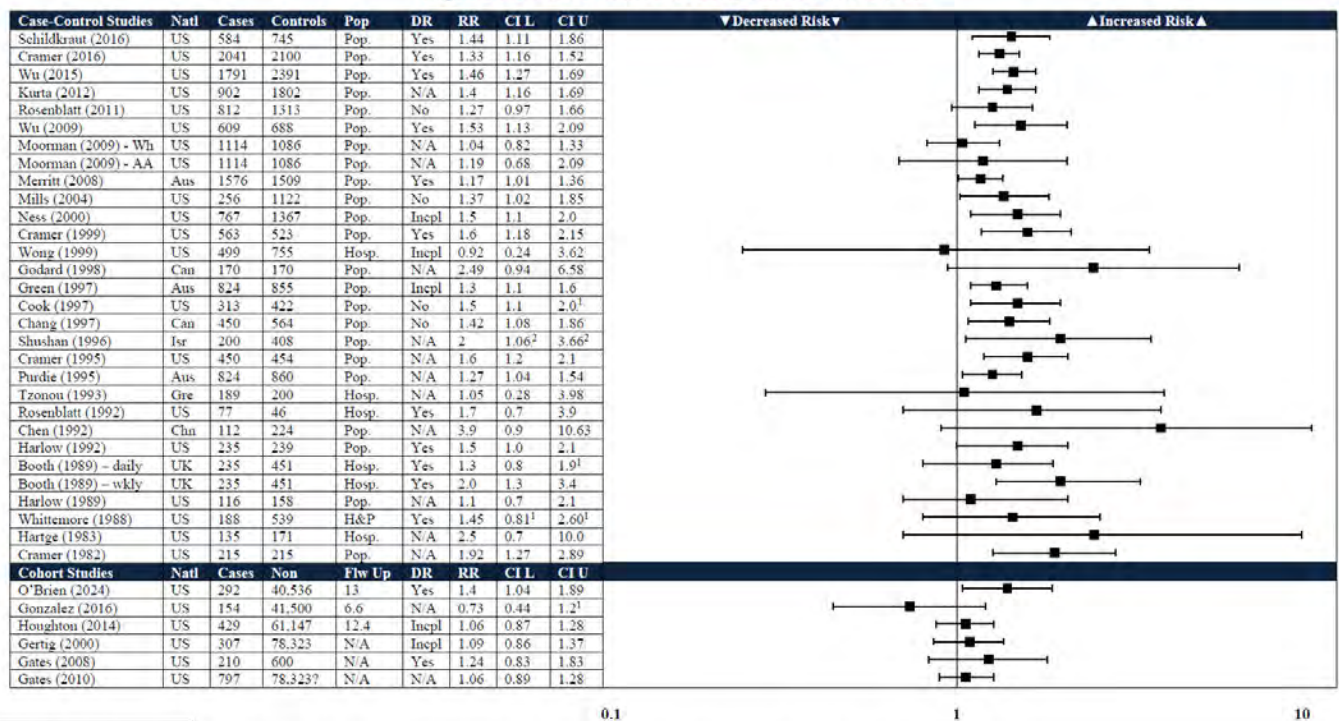
A cohort study follows a group of people with defined characteristics, such as talcum powder exposure, and who are followed to determine incidence of an outcome, in this case development of ovarian cancer. Cohort studies can be retrospective or prospective. They can calculate rates of disease in exposed and unexposed individuals for multiple outcomes over time. Potential disadvantages of cohort studies include the requirement of large number of subjects for rare exposures and outcomes and long duration of follow up for certain conditions. (Song et al. 2010). These disadvantages apply to the study of talc and ovarian cancer. Narod estimated that, for a cohort study to be properly powered to accurately predict the risk associated with talc use and ovarian cancer, as many as 200,000 women may be necessary. (Narod 2016).

A meta-analysis combines the results from previous studies to derive conclusions from a larger set of data. Outcomes from a meta-analysis may include a more precise estimate of the effect of treatment or exposure (talcum powder) than any individual study contributing to the pooled analysis. (Haidich (2010)). A meta-analysis weights the strengths of the studies before combining the data, unlike a pooled study. A meta-analysis can be especially useful to review a complex, sometimes conflicting body of literature.

A randomized control trial, in which participants are divided by chance into separate groups to compare different interventions, is considered the gold standard in some research situations. However, it would be unethical and impractical to conduct a prospective randomized control clinical trial to compare the outcomes of women who did and did not use genital talcum powder because of its known carcinogenic potential.

For this project, I reviewed all epidemiological studies related to talcum powder and ovarian cancer, but concentrated on the cohort studies, the meta-analyses, and more recent high-quality case-control studies. I critically analyzed factors such as study design, journal quality, number of subjects, length of follow-up, and potential biases. The following forest plots, prepared at the direction of Anne McTiernan, MD, PhD, are helpful presentations of relevant data from epidemiological studies.

Figure 2: Case-Control and Cohort Studies

<sup>1</sup> Corrected data-point from study text (report figure: Cook 1997 CI Upper 2.3; Gonzalez CI Upper 1.21; Booth 1989 CI Upper 1.0; Whittemore CI p=0.06).<sup>2</sup> Corrected data-point from defense expert report(s) (report figure: p=0.04).

## Case-Control Studies

There are numerous case-control studies. Overall, the case-control studies are consistent showing a 30-50% increase in risk of ovarian cancer with talcum powder use. I found the most recent ones to be the most useful, based on their size and quality of design. Several are summarized below: A study by Wu published in 2015, evaluated 1701 women with EOC in California. The conclusion of this study found that talc significantly increased the risk of ovarian cancer – 40% in whites, 20% in Hispanics, and 56% (not statistically significant) in African Americans. The number of African Americans with ovarian cancer was only 128 and may account for the non-significant increase. (Wu et al. 2015).

Cramer published a recent case-control study of nearly 4,000 women in Massachusetts and New Hampshire with ovarian cancer and found that genital use of talcum powder, either alone or in combination with body use, was associated with a statistically significant elevated epithelial ovarian cancer risk (OR 1.33). Risk increased with frequency and duration of use. Talcum powder use increased risk for serous and endometrioid tumors with the dose response most apparent for invasive serous cancer. (Cramer et al. 2016).

A multi-center study sponsored by National Cancer Institute of epithelial ovarian cancer in African-American women, a group with a high prevalence of talcum powder use, determined that regular genital powder use was associated with an increased risk of epithelial ovarian cancer (OR 1.44). A dose-response relationship was found for duration of use and number of lifetime applications ( $P < 0.05$ ). Additionally, talcum powder use was common (62.8% of cases and 52.9% of controls). (Schildkraut et al. 2016).



### **Cohort Studies**

The Nurses' Health Study (NHS I) is a prospective study of 121,700 nurses who were aged 30-55 years at enrollment in 1976 and followed through 1996 at the time of the publication. In the NHS, talcum powder use was ascertained once in 1982, the same year as the first case-control study showing an association of talc use with ovarian cancer. (Cramer et al. 1982). The follow up period for this study was 12.9 years. The study concluded there was no overall association with talc "ever use" and epithelial ovarian cancer. However, there was a statistically significant increased risk of invasive serous ovarian cancer (40%) that was higher with more frequent talcum powder use. The short period of follow up may not account for all ovarian cancer cases due to latency considerations between talcum powder usage and the development of ovarian cancer. (Gertig et al. 2000). A second report of the Nurses' Health Study (NHS II) in 2010 did not find a statistically significant increased risk with talcum powder usage, either epithelial cancer as a whole or serous subtype. (Gates et al. 2010).

The Women's Health Initiative (WHI) enrolled 93,676 women from 1993-1998. Women were eligible if they were aged 50 to 79 (mean 63.3 years) at enrollment and postmenopausal. Mean follow-up was 12.2 years. Use of powder on the genitals was associated with 12% increased risk of ovarian cancer, though this was not statistically significant. Limitations of this study include lack of information regarding oophorectomy and recall bias regarding history of talc "ever use". Additionally, the short follow-up may not account for all cases of ovarian cancer. Information regarding the frequency or duration of powder usage was not obtained. (Houghton et al. 2014).

The Sister Study (2003-2009) followed 50,884 women in the US and Puerto Rico who had a sister diagnosed with breast cancer. At enrollment, participants were asked about douching and talcum powder use in the previous twelve months. During follow-up (median 6.6 years) 154 women reported a diagnosis of ovarian cancer but only seventeen of those reported talc use. The authors determined that there was little association between baseline talcum powder use and subsequent ovarian cancer. Douching at baseline, more common in talc users, was associated with increased risk. All ovarian cancers were grouped together. Limitations of this original study include: 1) talc use was only obtained at baseline and was uncommon (analysis was based on only 17 cases), 2) no histologic information was obtained, so it is impossible to analyze relationship to serous subtype, 3) no risk elevation has ever been reported with dusting of diaphragm, cervical cap, or sanitary napkins, and 4) the short follow-up fails to account for the latency period. (Gonzalez et al. 2016).

All of the original cohort studies are limited by lack of power, failure to make the appropriate queries, selection bias, and short follow-up.

Fortunately, the Sister Study has been updated with more detailed information about the use of douche and genital talc, which was obtained in the fourth follow-up questionnaire (2017-2019). (O'Brien, et al. J Clin Oncol 00:1-15 (2024)). The authors used models that adjusted for exposure misclassification, and genital talc use was positively associated with ovarian cancer (HR range, 1.17-3.34). In women who were frequent users, the hazard ratio was 1.81 (1.29 to 2.53), and in women who were long-term genital talc users, the hazard ratio was 2.01 (1.39 to 2.91). Genital use of talcum powder by women during their 20s and 30s found the greatest increased risk. This study considered recall bias and found an increased risk of ovarian cancer both with and without correction for it.

This study was accompanied by an editorial by Harris et al. (2024), also in the *Journal of Clinical Oncology*, with a takeaway stating, “Given that genital powder use and douching are modifiable exposures potentially associated with a highly fatal disease, these data suggest that people at risk for ovarian cancer, particularly those in their 20s and 30s, should be made aware of the potential risks.” The editorial additionally states that “Primary care providers and gynecologists should consider addressing routine genital powder use and douching with their patients in a manner that addresses potential risks....”

The same day this paper was published, the American Society of Clinical Oncology in *ASCO Perspective* addressed this study, stating, “‘This study underscores the potential risks associated with intimate care products, particularly genital talc. The evidence adds to a growing body of literature that suggests such products could contribute to an increased risk of ovarian cancer, especially among frequent users and those using these products in their 20s and 30s,’ said ASCO Expert Fumiko Chino, MD, Radiation Oncologist at Memorial Sloan Kettering Cancer. ‘Despite challenges in assessing exposure history and biases inherent in retrospective data, our findings are robust, showing a consistent association between genital talc use and ovarian cancer,’ said lead study author Katie M. O’Brien, Ph.D., researcher at the Epidemiology Branch of the National Institute of Environmental Health Sciences. ‘This study leverages detailed lifetime exposure histories, and the unique design of the Sister Study, to provide more reliable evidence that supports a potential association between long-term and frequent genital talc use and ovarian cancer.’”



### Meta-Analyses and Pooled Studies (All Ovarian)

Meta-Analyses	Studies	Cases	DR	RR	CIL	CIU	▼ Decreased Risk ▼	▲ Increased Risk ▲
Woolen (2022)	11	6542	Yes	1.47	1.31	1.65		
Taher (2018)	27	17,149	Yes	1.28	1.2	1.37		
Penninkilampi (2018)	27	14,311	Yes	1.31	1.24	1.39		
Berge (2018)	27	N/A <sup>1</sup>	Yes	1.22	1.13	1.3		
Langseth (2008)	20	N/A <sup>1</sup>	N/A	1.35	1.26	1.46		
Huncharek (2003)	16	5260	No <sup>2</sup>	1.33	1.16	1.45		
Cramer (1999)	14	3834	N/A	1.4	1.2	1.5		
Gross (1995)	10 <sup>3</sup>	1509	N/A	1.29	1.02	1.63		
Harlow (1992)	6	1106	N/A	1.3	1.1	1.6		
Pooled Meta-Analyses	Studies	Cases	DR	RR	CIL	CIU		
Terry (2013)	8	8,525	Yes	1.24	1.15	1.33		
O'Brien (2020)	4	2168	No	1.08	0.99	1.17		
↳ Patent Reproductive Tract	4	1384	Yes	1.13	1.01	1.26		
Davis (2021)	5	AA:620	No	1.22	0.97	1.53		
		Wh:2800		1.36	1.19	1.57		

0.5

1

2

### Meta-Analyses and Pooled Studies

Five meta-analyses addressed the relationship between genital talcum powder use and ovarian cancer and each of these found a statistically significant relationship. (Berge, 2018, Penninkilampi 2018, Taher 2019, Davis 2021, Woolen 2022). The comprehensive meta-analysis by Penninkilampi and Eslick, published in 2018, included 24 case-control (13,421 cases) and three cohort studies (890 cases). The authors found that “any” perineal talc use was associated with an increased risk of ovarian cancer (OR = 1.31; 95% CI = 1.24, 1.39). More than 3600 lifetime applications (OR = 1.42; 95% CI 1.25, 1.39) were slightly more associated with ovarian cancer than <3600 (OR = 1.32; 95% CI = 1.15, 1.50). An association with “ever use” of talc was found in case-control studies (OR = 1.35; 95% CI = 1.27, 1.42), but not cohort studies (OR 1.06; 95% CI = 0.90, 1.25). However, cohort studies did find an association between talc use and invasive serous ovarian cancer (OR = 1.25; 95% CI = 1.01, 1.55). The authors stated that case-control studies are preferred in this situation because statistical power is easier to obtain with the larger number of ovarian cancer cases and controls and the lengthy follow-up necessary for a prospective study is not required. I agree. The authors determined that perineal talc use is associated with a 24%–39% increased risk of ovarian cancer that is suggestive of a causal association. (Penninkilampi and Eslick 2018).

Of note, the Penninkilampi meta-analysis was identified as one of the “best articles” of 2018 on ovarian cancer in *Obstetrics and Gynecology*, the journal published by the American College of Obstetricians and Gynecologists. (Wright 2018).

In addition to Penninkilampi, the four other recent meta-analyses described similar findings. Berge determined that the summary relative risk (RR) for ever use of genital talc and ovarian cancer was 1.22 [95% confidence interval (CI): 1.13–1.30]. (Berge 2018). Taher, a meta-analysis commissioned by Health Canada, also found a statistically significant positive association between perineal use of talc powder and ovarian cancer [OR: 1.28 (95% confidence interval (CI): 1.20 - 1.37)]. (Taher 2019).

Davis (2021) focused on African American women as genital talcum powder use is more common in this group. Using data from five studies conducted by the Ovarian Cancer in Women of African Ancestry Consortium, the investigators found among African American women an increased risk with genital talcum powder use and ovarian cancer (OR = 1.22; 95% CI: 0.97-1.53) and for high grade serous (OR = 1.31; 95% CI: 1.01-1.71). For white women, the odds ratio for ever use of talcum powder and ovarian cancer was 1.36 (95% CI: 1.19-1.57) and for high grade serous 1.33 (95% CI: 1.1-1.56). For all women, the results were an increased risk of 32% both for all ovarian cancer and high grade serous, (OR = 1.32; 95% CI: 1.17-1.48) and (OR = 1.32; 95% CI: 1.15-1.51) respectively.

Woolen (2022), a systematic review and meta-analysis, found a statistically significant increased risk of ovarian cancer with frequent use of perineal talcum powder (defined as  $\geq 2$  times per week (OR = 1.47; 95%, CI 1.31-1.65). Woolen reported data regarding daily use from the Nurse's Health Study (NHS) which found a statistically significant increased risk in all women (1.27, 95%, CI 1.09-1.49) and in women with patent fallopian tubes (1.40, 95%, CI 1.17-1.68).

In addition to these meta-analyses, O'Brien published a pooled study in 2020. This study pooled data from cohort studies: Nurse's Health Study I and II (NHS), Women's Health Initiative (WHI), and the Sisters Study. (O'Brien 2020, O'Brien Supp. E-Tables 2020, Gossett 2020). This study included 252,745 subjects; 1884 developed confirmed ovarian cancer. The information obtained in these studies on talcum powder usage patterns was different in each of these cohorts. However, the authors attempted to standardize these discrepancies by combining groups across the studies. The authors acknowledged the direct physical pathway between exposure of talcum powder on the perineum and the fallopian tubes and ovaries.

The overall relative risk for "ever use" versus "never use" of genital talcum powder was 1.08 (CI 0.99-1.17). However, significantly elevated risk was found in women with patent reproductive tracts (RR 1.13; CI 1.01-1.26). In addition, a statistically significant increased risk was noted in frequent users (at least weekly) and women who had previously used hormone therapy. There were limitations and deficiencies in this study that are discussed in Letters to the Editor. (Cramer & Harlow, Letters to the Editor with Reply, 2020).

### **Summary of Epidemiological Evidence**

When looking at epidemiological studies in their totality, the data demonstrates a consistent, replicated, and statistically significant increased risk of developing epithelial ovarian cancer with perineal talcum powder use. Invasive serous carcinoma is the most commonly associated histologic subtype. The risk elevation is 20-60%. This risk is stable among case-control studies, one cohort study, and all meta-analyses/pooled analyses over several decades. Recall and confounding bias in case-control studies appear to have minimal impact. (Penninkilampi and Eslick 2018; Langseth et al. 2008). There appears to be no significant publication bias. (Berge et

al. 2017; Penninkilampi and Eslick 2018). Meta-analysis is the most reliable and scientifically valid epidemiological methodology to evaluate the association of talcum powder usage with ovarian cancer risk.

## **VI. ASBESTOS, FIBROUS TALC, AND OTHER CONSTITUENTS OF TALCUM POWDER**

Asbestos is one of the most potent carcinogens known. All forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite) are carcinogenic to humans. (IARC 2012) The conclusions reached by International Agency for Research on Cancer (IARC) about asbestos and its carcinogenic risks apply to these six types of asbestos wherever they are found and includes talc containing asbestiform fibres (fibrous talc or talc fibers). (IARC 2012) Asbestos was first linked to pulmonary mesothelioma in 1935 (Gloyne 1935) and has been known to be an etiologic factor for ovarian cancer since 1965. (Graham and Graham 1967).

According to IARC, asbestos causes mesothelioma of the lung, larynx, and ovary. Based on multiple positive cohort mortality studies of women with heavy occupational exposure to asbestos, IARC's Working Group determined there is a causal association between asbestos exposure and ovarian cancer. The IARC 2012 Monograph on asbestos and fibrous talc states, "consumer products (e.g., cosmetics, pharmaceuticals) are the primary source of exposure to talc for the general population. Inhalation and dermal contact (i.e., through perineal application of talcum powders) are the primary routes of exposure." (IARC 2012).

A recent meta-analysis by Nowak (2021) found that there was a significant increased risk in ovarian cancer following occupational asbestos exposure (OR=1.88 (1.47, 2.39) and concluded that asbestos exposure is a cause of ovarian cancer. The EPA has also concluded that ovarian cancer is a health effect caused by exposure to asbestos. (EPA, Fed. Reg., Vol. 88, No. 141 (2023).

The scientific literature demonstrates that talc can contain asbestos and fibrous talc. (Cralley et al. 1968; Rohl et al. 1976; Lockey 1981; Paoletti et al. 1984; Blount 1991; Werner 1982). Blount (1991), Johnson & Johnson internal testing results and documents, and testing results of Dr. William Longo and Dr. Mark A. Rigler have demonstrated that talcum powder products, including Johnson's Baby Powder and Shower to Shower, may contain asbestos. (Blount 1991; "Deposition of Alice M. Blount, Ph.D., Circuit Court of the City of St. Louis State of Missouri, Case No.: 1522-CC10417-01" 2018; "Exhibit 28, Deposition of John Hopkins, Ph.D., In Re: Talcum Powder Prod. Liab. Litig., MDL No. 2378" 2018; "Exhibit 47, Deposition of Julie Pier, In Re: Talcum Powder Prod. Liab. Litig., MDL 2738" 2018; Longo & Rigler Expert Report (Feb. 2, 2019). Drs. Longo and Rigler found that 44 of 65 (68%) historical samples of Johnson's Baby Powder and Shower to Shower were positive for amphibole asbestos. These historical samples originated in the 1960s through the early 2000s. They found that 55 of 56 of these (98%) historical samples contained fibrous talc.

In October 2019, the FDA reported the results of testing conducted by AMA Analytical Services, Inc. on a bottle of Johnson's Baby Powder purchased in 2018. AMA identified chrysotile asbestos and talc fibers. These findings provide further data demonstrating the presence of asbestos and talc fibers in talcum powder products. (AMA Certificate of Analysis, October 11, 2019, Owen 2019).

Asbestos fibers and talc fibers exposure are known to cause ovarian cancer; their presence in Johnson & Johnson talcum powder products contributes to the carcinogenicity of the products through an established mechanism of inflammation, DNA damage, and genetic alterations. Asbestos and talc fibers may directly induce DNA damage mediated by reactive oxygen species. Fibers have also been shown to physically interfere with the mitotic apparatus, which may result in aneuploidy or polyploidy, and specific chromosomal alterations characteristic of asbestos-related cancer. In addition, persistent inflammation and macrophage activation can secondarily generate additional reactive oxygen species and reactive nitrogen species that can indirectly induce genotoxicity in addition to activation of intracellular signaling pathways, resistance to apoptosis, stimulation of cell proliferation, induction of epigenetic alterations, and activation of oncogenes/inactivation of tumor suppressor genes. (IARC 2012; Kane et al. 1996; Mossman 2018; Shukla et al. 2009; M. C. Jaurand 1997, 1989; M. Jaurand 1991).

In addition to asbestos and fibrous talc, talcum powder products have been shown to contain nickel, chromium, and cobalt. (“Exhibit 47, Deposition of Julie Pier, In Re: Talcum Powder Prod. Liab. Litig., MDL 2738” 2018). Nickel and chromium are Group 1 carcinogens according to IARC. Cobalt is a Group 2b (or possible carcinogen) according to IARC. The inflammatory mechanism for carcinogenesis for these metals is similar to that described for asbestos, fibrous talc, and platy talc.

I have also seen the list of “fragrance chemicals” added to Johnson’s Baby Powder and Shower to Shower products, as well as the expert report of Dr. Michael Crowley. Many of these chemicals are known to be irritants, toxins, and carcinogens. Some have been shown to be harmful to the reproductive organs and function. These chemicals would be expected to accompany the talcum powder as it migrates or is transported through the genital tract to the fallopian tubes and ovaries. At least some of these chemicals would also be expected to be absorbed through the vaginal mucosa. These chemicals likely contribute to the inflammatory properties, toxicity, and carcinogenicity of these talcum powder products.

The presence of these constituents provides additional support for the mechanism by which Johnson’s Baby Powder and Shower to Shower cause ovarian cancer, as demonstrated in the epidemiological literature.

## **VII. MIGRATION AND TRANSPORT OF TALC THROUGH THE GENITAL TRACT**

In the adult female, the peritoneal cavity communicates with the outside via the fallopian tubes, uterus, and vagina. It is an open system (Netter, Crum, Blaustein). This is apparent in literature describing normal female external genitalia. (Lloyd 2005). MRI evidence also demonstrates an open vagina even in its nondistended state. (Barnhart 2006). As such it is universally accepted in the gynecologic community that substances migrate and/or be transported in both directions.

Evidence to support the migration/transport of talc particles and fibers includes, but is not limited to:

1. Sperm: Sperm move more quickly through the genital tract than would be predicted from innate motility, indicating a transport mechanism. In addition, dead sperm and inanimate sperm particles (lacking flagella) are efficiently transported upwards through the uterus

and tubes. (Jones and Lopez 2006). This process involves directed uterine contractility that has been confirmed through research of intrauterine pressure measurements. (Kissler et al. 2004).

2. Carbon particles: Inert carbon particles were placed in the posterior vaginal fornix and observed in the fallopian tubes 28 and 34 minutes later (2 out of 3 patients tested). This research confirmed that sperm motility is not the chief factor in transport and that contractions of the uterus are likely involved in process of migration/transport of particles through the genital tract. (Egli and Newton 1961).
3. Retrograde menstruation: The transport of menstrual flow into the peritoneal cavity was first proposed by Sampson in 1927 and is now well-established as the mechanism for endometriosis initiation. The prevalence of retrograde menstruation has been described in 90% of investigated women. (Blumenkrantz et al. 1981; Halme et al. 1984).
4. Particulate radioactive material: Particulate radioactive material was placed in the posterior vaginal fornix. Twenty four hours later, radioactive material was present in the adnexa separate from the uterus in 2/3 of cases. The authors concluded that the transit of particles from the vagina to the peritoneal cavity and the ovaries “is probably the same for many chemical substances used for hygienic, cosmetic, or medicinal purposes, many of which may have potential carcinogenic or irritating properties . . . migration of certain chemical substances could play an important aetiological role in gynaecological diseases and especially in carcinoma of the ovary.” (Venter and Iturralde 1979).
5. Bathwater: Psooy in 2010 demonstrated that bathwater can become entrapped in the vagina in females with normal anatomy. (Psooy 2010).
6. “Uterine peristaltic pump”: Rapid and sustained sperm transport from the cervix to the fallopian tube is provided by uterine peristaltic contractions that can be visualized by vaginal sonography. (Kunz 1997; Zervomanoklakis et al. 2007).
7. Glove powder: Studies have demonstrated retrograde migration of starch after gynecological examination with powdered gloves. The authors concluded that: “Consequently, powder or any other potentially harmful substances that can migrate from the vagina should be avoided.” (Sjösten, Ellis, and Edelstam 2004).
8. Talc: Studies have documented the presence of talc particles in the adnexa, ovaries, and peritoneum. The authors of these studies have concluded that this occurs as a result of migration of talc particles from the vagina through the cervix, uterus, and fallopian tubes. (Henderson et al. 1971, 1979; D. W. Cramer 1999; Heller et al. 1996). Talc has also been noted in pelvic lymph nodes which could also occur through migration, absorption, or inhalation with transport through the lymphatic system. (Cramer et al. 2007). A follow-up to the 2007 study regarding the presence of talc in lymph nodes and other pelvic organs controls for contamination as a potential source of the talc particles seen. (McDonald 2019 AJCP).



The migration of particles, including talc, asbestos and other constituents of talcum powder products, from the perineum to the upper genital tract (tubes and ovaries) is a key element in the mechanism by which talcum powder products cause ovarian cancer. The evidence supporting this process is robust and universally accepted by the medical community.<sup>3</sup> (FDA Citizens Petition response 2014). I have considered the limited evidence to the contrary and find it non-persuasive.

In addition to perineal application resulting in migration and transport of particles through the genital tract, inhalation of these particles is another recognized route of exposure. (IARC 2012; W. E. Longo, Rigler, and Egeland 2017; Steiling et al. 2018; Cramer et al. 2007). With either of these routes, talcum powder components can also be directly absorbed into the lymphatic system and bloodstream.

## **VIII. INFLAMMATION AND MOLECULAR BASIS FOR CARCINOGENESIS OF TALCUM POWDER PRODUCTS**

The link between inflammation and cancer has been recognized since the 1800s. Inflammation and oxidative stress increase the risk of cancer, including ovarian cancer. It has been known since the 1940's that talc causes inflammation. (Eberl and George 1948).

There is an increased risk of malignancy with many inflammatory processes, including infection, autoimmune diseases, hypoxia, and chemical and physical agents (including talc and asbestos).

1. Virchow noted inflammatory cells (leukocytes) in neoplastic tissue as early as 1863.
2. Inflammation resulting from talcum powder use has been proposed as a potential mechanism for the association with EOC. (Ness 1999; Balkwill & Mantovani 2001; Phung et al. 2022).<sup>4</sup>
3. Both tumor cells and inflammatory cells produce cytokines and chemokines which can contribute to cancer growth and spread.
4. Cytokines from inflammation/oxidative stress can influence multiple steps of the neoplastic process: survival, growth, mutation, proliferation, differentiation, and movement of cells. (Balkwill and Mantovani 2001; Reuter et al. 2010; Crusz and Balkwill 2015; Kiraly et al. 2015; Fletcher et al. 2019). Below are examples of inflammatory cytokines and their influence on cancer:
  - a. Tumor necrosing factor (TNF) can induce reactive oxygen (nitric oxygen (NO)) which can cause DNA damage. DNA damage can also occur by inhibiting cytochrome p450.

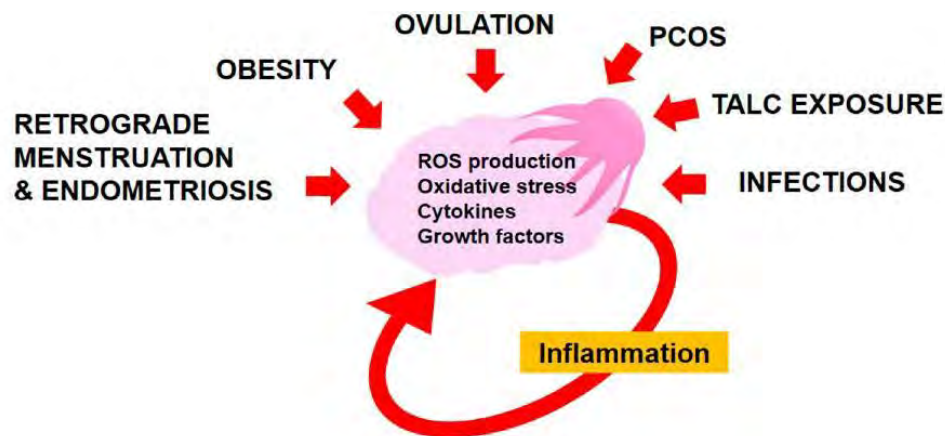
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<sup>3</sup> FDA states that the “potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable.

<sup>4</sup> Richard Zazenski, Director Product Safety for Luzenac, states in an email to Bill Ashton, on September 30, 2004: “I came across this paper this morning published in the April 2004 journal “Human Reproduction”, an official journal of the European Society for Human Reproduction and Embryology. It offers some compelling evidence **in support of the ‘migration’ hypothesis**. Combine this ‘evidence’ with the theory that talc deposition on the ovarian epithelium initiates epithelium inflammation – which leads to epithelium carcinogenesis – and you have a potential formula for NTP classifying talc as a causative agent in ovarian cancer.” (“IMERYS137677-IMERYS137690” 2004).

- b. Migration inhibitory factor (MIF) can inhibit the activity of p53 which is a tumor suppressor.
  - c. IL-6, IL-1, IL-8 are all known to stimulate tumor cell proliferation and survival.
  - d. Multiple inflammatory cytokines (TNF, IL-1, IL-6, TGF beta 1) can stimulate angiogenesis.
  - e. TNF and IL-1 stimulate adhesion to promote invasion and metastasis of cancer cells.
5. Inflammation/oxidative stress affects all phases of cancer development and growth and is implicated in pathogenesis of ovarian cancer. This leads to decreased apoptosis and increased anaerobic metabolism. Anaerobic metabolism leads to an acidic state which facilitates cancer growth. (G. Saed 2017; G. M. Saed et al. 2010; Jiang et al. 2011; Shan and Liu 2009; Freedman et al. 2004).
  6. Talcum powder causes inflammation/oxidative stress both *in vitro* and *in vivo* (in both animal and human tissues). (Eberl and George 1948; Graham and Jenkins 1952; Hamilton et al. 1984; Buz'Zard and Lau 2007; Shukla et al. 2009; Fletcher et al. 2019; Akhtar 2010, 2012; Mandarino et al. 2020; Emi et al. (2021); "NTP Toxicology and Carcinogenesis Studies of Talc (CAS No. 14807-96- 6) (NonAsbestiform) in F344/N.Rats and B6C3F1 Mice (Inhalation Studies)" 1993; Keskin et al. 2009).
  7. Although the literature is still somewhat contradictory, aspirin and other non-steroidal anti-inflammatory drugs have been shown to prevent and treat certain types of cancer, particularly colorectal. (Trabert et al. 2019; Rayburn, Ezell, and Zhang 2009; Chan et al. 2005).
  8. Fletcher et al. describes induction of gene point mutations after Johnson's Baby Powder exposure, corresponding to known single nucleotide polymorphisms (SNPs) in normal and ovarian cancer cells *in vitro*. These SNPs alter the activities of key oxidant enzymes and enhance the pro-oxidant state. This process of gene mutation is part of the carcinogenic cascade initiated by inflammation and oxidative stress. These results are consistent with other *in vitro* studies. (Shukla et al. 2009, Buz'Zard and Lau 2007, Akhtar et al. 2010, 2012; Mandarino et al. 2020; Emi et al. (2021). Harper 2023 reported cell proliferation, neoplastic transformation and p53 mutations when cells in culture were exposed to Johnson's Baby Powder.
  9. In summary, inflammation/oxidative stress has been well established as a significant factor in the development of cancer, including epithelial ovarian cancer. Inflammation/oxidative stress facilitates cancer growth at multiple steps. A recent review article provides a comprehensive discussion of the role of inflammation in the initiation, development, progression, metastasis, and chemoresistance of EOC. This paper identifies talc exposure as one source of inflammation in the ovary and fimbria. (Savant 2018).





**Figure 1.** Sources of inflammation in the ovary and fimbriae. Ovulation, retrograde menstruation, endometriosis, infections, exposure to talc, Polycystic Ovarian Syndrome (PCOS), and obesity result in exposure of the ovary and fimbriae to reactive oxygen species (ROS), oxidative stress, cytokines, and growth factors, generating an inflammatory response that leads to additional production of ROS and cytokines in the ovary. Unresolved, chronic inflammation is a critical risk factor for tumor initiation.

(Savant 2018).

## IX. CORNSTARCH

Since 1948 with a publication from Johnson & Johnson's own laboratory, it has been clear that starch is a safer alternative to talc for use on surgical gloves. Starch, unlike talc, is not an irritant and can be absorbed readily. (Eberl and George 1948).

A review paper by Whysner and Mohan in 2000 evaluated the available literature regarding the effects of cornstarch in the peritoneal cavity, comparing the potential risk of ovarian cancer with cornstarch versus talc. Unlike talc, the authors noted that 1) cornstarch is capable of being removed by physiologic processes from the peritoneal cavity, 2) cornstarch contains no asbestos, and 3) epidemiologic studies reviewed found no relationship between cornstarch powder use and ovarian cancer. The authors concluded that any increased risk for ovarian cancer as a result of perineal exposure to cornstarch was biologically implausible. (Whysner and Mohan 2000).

## X. DETERMINING WHETHER A RISK FACTOR IS CAUSATIVE

Although Bradford Hill factors are primarily an epidemiologic tool, the general principles provide a framework for clinical doctors to assess whether diseases like cancer can be caused by a particular agent, condition, or practice. The Bradford Hill factors are not a formal checklist. These considerations are the same as those that I apply regularly, both in my clinical practice and research, and are similar to the principles of evidence-based medicine. (Brewster 2017 in DiSaia and Creasman, Fedak 2015).

The factors as described by Bradford Hill are:

1. Strength (effect size): A small association does not mean that there is not a causal effect, though the larger the association, the more likely that it is causal.
2. Consistency (reproducibility): Consistent findings observed by different persons in different places with different samples strengthens the likelihood of an effect.
3. Specificity: Causation is more likely if there is a specific disease with no other likely explanation. Most frequently used example is a specific bacterium causing a particular disease (e.g., *M. tuberculosis* causes TB and *T. pallidum* causes syphilis). The more specific an association between a factor and an effect is, the bigger the probability of a causal relationship, but this is not necessarily required.
4. Temporality (and Latency): The effect must occur after the cause (and if there is an expectant delay between the cause and expected effect, then the effect must occur after that delay).
5. Biological gradient (Dose-response): Greater exposure should generally lead to greater incidence of the effect. There may also be a minimum level of exposure necessary (threshold). As a general principle of pharmacology and toxicology, the likelihood of a response increases with longer and more frequent exposure to an agent (dosage). (Klaassen and Doull 2013).
6. Plausibility: A plausible mechanism between cause and effect is helpful (but Hill noted that knowledge of the mechanism can be limited by current knowledge). Knowledge and understanding of the biological mechanisms changes over time.
7. Coherence: Coherence between epidemiological and other research data/findings increases the likelihood of an effect. Coherence is the idea that an alleged association should not conflict with substantive knowledge that exists regarding the disease at issue.
8. Experiment: "Occasionally it is possible to appeal to experimental evidence". This factor often refers to support from animal and clinical research with sound methodology. Has there been an attempt to collect data to analyze a cause and effect relationship? Do studies use controls when feasible? Are experiments reproducible? Are there ethical limitations?
9. Analogy: The effect of similar factors may be considered. All the rules relating to scientific methodology must be employed at each stage of the analogy. (Fedak et al. 2015).

I considered these aspects of a causal relationship in determining whether talcum powder products cause ovarian cancer.

### **Strength**

Overall, the studies show a 1.3-1.4 odds ratio of increased risk of ovarian cancer among perineal talc users. A recent and most complete meta-analysis determined an odds ratio of 1.31 with any perineal talc use and the development of ovarian cancer. An association with ever use of talc was found in case-control studies (OR = 1.35) and in the newest cohort study publication (HR range = 1.17-3.34) when adjusted for exposure misclassification. Cohort studies also found an association between talc use and invasive serous type ovarian cancer. (Penninkilampi and Eslick 2018). If invasive serous ovarian cancer or frequent use is considered, the association is even stronger.

Strength is also supported when there are numerous studies with consistent findings as in the case of talcum powder and the association with ovarian cancer. In general, many of the studies are well conducted, numerous and consistent, making the strength of the association valid. When looking at causation of a relatively rare disease like ovarian cancer, this magnitude of risk is statistically and clinically significant and not unusual. With ovarian cancer, a disease which is difficult to diagnose and deadly, any preventable risk factor (talcum powder) should be deemed critically important and avoided.

### **Consistency**

The magnitude of risk has been consistent over four decades, across various geographic populations and throughout the United States, Canada, and Australia. Results are generally consistent across case-control, meta-analysis, and pooled analysis studies. I deemed the consistency and replication of the studies to be important in my causation analysis.

### **Specificity**

The most compelling disease associated with talcum powder use is epithelial ovarian cancer, therefore specificity for a disease is demonstrated. The most recent cohort publication also addressed specificity as there was no association between genital talc use and increased risk of uterine or breast cancer.

### **Temporality**

Exposure to talcum powder and the resultant development of ovarian cancer meets the temporality consideration that the outcome follows the event. The average latency period between exposure to talc and diagnosis of ovarian cancer is at least twenty years. This is consistent with other cancers known to be caused by chemicals and/or toxins. (Purdie et al. 2003; Okada 2007).

### **Biologic Gradient (Dose-response)**

Exposure is difficult to quantify with talcum powder applications with regard to how much is used, where it is concentrated, and how much actually reaches the tubes and ovaries; Many of the studies did not obtain the necessary information to evaluate dose response and lacked adequate power to assess dose-response accurately. Despite the lack of sufficient information in many studies, recent meta-analyses/pooled study and a case-control studies do show a dose response, using frequency and duration of use as parameters. (Penninkilampi and Eslick 2018; Cramer et al. 2016; Schildkraut et al. 2016; Terry et al. 2013; Wu et al. 2015). Data from the Nurse's Health Study demonstrated a dose response between non-users, less frequent users, and daily users. (Woolen 2022, Supp. Table 1). Similarly, the O'Brien (2024) publication looking at the Sister Study cohort found an even higher increased risk with frequent use and long duration of use. Modern medicine also recognizes that a monotonic dose-response curve is often overly simplistic (e.g., asbestos demonstrates a threshold rather a linear dose-response). Response can vary based on unique characteristics of the given population, exposure routes, molecular endpoints, individual susceptibility and synergistic or antagonistic effects of cumulative exposures. (Fedak et al. 2015). Given the limitations of the data, I consider this a less important factor when compared to the strength of the association, consistency, and the biological mechanism.

### **Plausibility**

The general mechanism by which talcum powder products cause ovarian cancer is established as

an inflammation-induced process. It is well-accepted that particles reach the fallopian tubes and ovaries through migration/transport through the genital tract. These particles can also reach the pelvic organs through inhalation. The particles elicit an inflammatory tissue response and initiate a cascade of events and pathways at the cellular level that result in cancer formation. This process is well-described by the medical and scientific community. In addition, as previously discussed in this report, various components of talcum powder products, including asbestos and fibrous talc, are known carcinogens and known to cause cancer by similar mechanisms.

### **Coherence**

The findings and conclusions from epidemiological, animal, and *in vitro* studies are coherent with what is known about ovarian cancer. There is also consistency with what is known about other gynecological malignancies and other cancers induced by environmental and occupational exposures.

### **Experiment**

Causation of ovarian cancer by talcum powder is supported by laboratory (*in vitro* and *in vivo*) experiments. Research is ongoing which will further elucidate specific processes.

Prospective randomized controlled clinical trials to evaluate talcum powder products and their relationship to ovarian cancer are not feasible for a variety of ethical and methodological reasons. These include the recognized toxicity of talc, asbestos, and other constituents of talcum powder, the absence of therapeutic benefit, the long latency period, and the seriousness of ovarian cancer.

### **Analogy**

As with consistency, plausibility, and coherence, the association between talcum powder and ovarian cancer is analogous to other diseases caused by various and specific carcinogens. For example, smoking causes lung cancer, asbestos causes mesothelioma and ovarian cancer, sun exposure causes skin cancer, and HPV causes cervical cancer. All of these cancers are the result of an inflammatory process initiated by a foreign agent.

Applying these Bradford-Hill guidelines and the principles of evidence-based medicine, it is my opinion that the genital use of talcum powder can cause ovarian cancer. In recent years, other scientists, physicians, and organizations have reached this same conclusion. (Health Canada 2021; IARC 2012; Penninkilampi and Eslick 2018; Schildkraut et al. 2016; Cramer et al. 2016).

Health Canada published its comprehensive final assessment on the health risks associated with talcum powder usage in the genital area, reaching similar conclusions described in my analysis. (Health Canada Assessment 2021). The human health portion of Health Canada's assessment underwent external peer review. These conclusions include:

1. "With regards to perineal exposure, analyses of the available human studies in the peer-reviewed literature indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer." (iii)
2. "The available data are indicative of a causal effect." (iii)
3. "Although there are uncertainties related to bias [in the epidemiological studies], there is confidence in the robustness of the available database for use in characterizing cancer risk

attributed to talc exposure. Furthermore, the available data are indicative of a causal relationship.” (36)

4. Referencing at least 15 documents and articles, “[p]articles of talc are able to migrate into the pelvis and ovarian tissue...” (33)
5. “[T]here is support for an association on inflammation and increased risk of ovarian cancer.” (20-21)
6. “With respect to talc and induction of tumours, local chronic irritation leading to an inflammatory response is one possible mechanism of tumour progression that is frequently cited in the literature.” (20-21)

## **XI. SUMMARY OF GENERAL OPINIONS**

The opinions in this report are provided to a reasonable degree of medical and scientific certainty. A summary of these opinions follows:

1. Based on epidemiological studies, the established biological mechanism, and evidence of the presence of asbestos, fibrous talc, and other known carcinogens, talcum powder products cause epithelial ovarian cancer in some women. The genital use of talcum powder products presents a significant risk factor for ovarian cancer for *all* women who use the products.
2. When looking at epidemiological studies in their totality, the data demonstrates a consistent, replicated, and statistically significant increased risk of developing epithelial ovarian cancer with perineal talcum powder use.
3. Asbestos and fibrous talc are known human carcinogens, including ovarian cancer (IARC 2012) and have been shown to be present in Johnson’s Baby Powder and Shower to Shower. In addition, other known constituents of talcum powder products (including nickel, chromium, and cobalt) are carcinogenic, and their presence likely contributes to the cancer-causing properties of talcum powder products.
4. The extensive number of fragrance chemicals added to the talcum powder products likely contributes to the inflammatory properties, toxicity, and carcinogenicity of these products.
5. The migration/transport of talcum powder and its constituents, to the upper genital tract (tubes and ovaries) is a key element in the mechanism by which talcum powder products cause ovarian cancer. The evidence supporting migration is robust and universally accepted by the gynecologic community. In addition to perineal application resulting in migration and transport of particles and fibers through the genital tract, inhalation of these particles is another recognized route of exposure.
6. Inflammation/oxidative stress is an early and essential step in the molecular process by which talcum powder products cause ovarian cancer.
7. Cornstarch is a safer alternative to talcum powder.
8. Talcum powder use is a preventable causative risk factor for EOC.

Based on my education, training, experience and expertise in ovarian and other gynecologic cancers, review of the totality of the evidence, analysis and weighing the data in the context of Bradford Hill and the principles of evidence-based medicine, it is my professional opinion to a reasonable degree of scientific and medical certainty that Johnson's Baby Powder and Shower to Shower products cause epithelial ovarian cancer in some women. The use of talcum powder products presents a significant risk factor for ovarian cancer in *all* women who use the products.

## **XII. CASE-SPECIFIC OPINIONS: ANNA GALLARDO**

I reviewed the available medical records for Plaintiff Anna Gallardo. I also reviewed the Plaintiff Profile Form (PPF), Dr. Godleski's report, and deposition testimony in considering my opinion regarding causation in this case. My opinions are based on my education, training, and experience, as well as the General Causation facts and opinions previously provided. After completing my review, it is my opinion that Ms. Gallardo's use of talcum powder products on her body, including her genital area, is a substantial contributing cause of her ovarian cancer.

Ms. Gallardo (D.O.B. [REDACTED] 1952) was [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

According to the Plaintiff's Profile Form and deposition, Ms. Gallardo [REDACTED]  
[REDACTED].

I have also reviewed Dr. Godleski's pathology expert report. Dr. Godleski confirmed the diagnosis of high grade endometrioid carcinoma. In addition, in 66 slides and 5 blocks, he found 208 talc particles/fibers and 30 tremolite fragments/fiber. Dr. Godleski found to a reasonable degree of medical and scientific certainty that "the talc and tremolite particles/fibers found in the tissues of Ms. Gallardo are contributory evidence for a causal link between the presence of these materials and the development of her ovarian cancer."

In formulating my opinion regarding causation of Ms. Gallardo's ovarian cancer, I performed a differential diagnosis based on answers to the following questions:

1. Did the plaintiff have ovarian cancer? Yes, this was confirmed with her surgery and in pathologic review.
2. Was the histologic subtype consistent with those associated with talcum powder products? Yes, high grade endometrioid adenocarcinoma has been found to be associated with genital talcum powder use in multiple studies.
3. Did the plaintiff have a history of sufficient perineal use of talcum-containing products? Yes,  
[REDACTED].
4. Was the timing of her diagnosis consistent with a talcum powder effect? Yes, she reports use beginning 45 years prior to the diagnosis of her ovarian cancer – more than the 20 years latency period that has been described with chemicals causing cancer and talcum powder use causing ovarian cancer.
5. Were there particles present in the tissues analyzed, lending support to causation? Yes. Although not a requirement, Dr. Godleski found evidence of talc particles/fibers and tremolite fragments/fibers in her pathologic tissue.



6. Were there protective factors present and, if so, what was their contribution to the development of ovarian cancer?

- Ms. Gallardo [REDACTED].
- She [REDACTED].

7. Did Ms. Gallardo have other risk factors?

- Genetic risk factors – Ms. Gallardo [REDACTED].
- Increasing age – Ms. Gallardo was average age for the diagnosis of epithelial ovarian cancer.
- Nulliparity and infertility – Ms. Gallardo [REDACTED].
- Endometriosis, polycystic ovarian syndrome – [REDACTED].
- Obesity – [REDACTED].
- Use of an intrauterine device – [REDACTED].
- History of pelvic inflammatory disease – [REDACTED].
- Hormone therapy – [REDACTED].
- Cigarette smoking – [REDACTED].

In summary, it is my opinion after reviewing the available medical records, the Plaintiff's Profile Form, Dr. Godleski's report, and deposition testimony that Ms. Gallardo's use of Johnson's Baby Powder on her body, including her genital area, is a substantial contributing cause of her ovarian cancer. My opinions are made to a reasonable degree of medical and scientific certainty. I reserve the right to amend or modify this report if new information becomes available. I reserve the right to review and comment on the reports and testimony of Defendants' expert witnesses.

# Exhibit A

**CURRICULUM VITAE**

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**Judith K Wolf, MD****PRESENT TITLE AND AFFILIATION**

Gynecologic Oncologist  
Locum Tenens  
01/2021 to present

Goshen Center for Cancer Care, Goshen, IN 4/2020- 6/2022  
Rochester General Hospital, Rochester NY 1/2021-12/2021  
Hershey Medical Cancer, Hershey PA 4/2022-7/2023  
Park Nicolett Minneapolis, MN 4/2023-10/2023

**CITIZENSHIP**

United States

**PREVIOUS WORK EXPERIENCE**

Gynecologic Oncologist  
Community Health Network  
Clearvista Parkway  
Indianapolis, IN  
06/2018 to 01/2021

Chief Medical Officer

ProvistaDx  
55 Broad St 18<sup>th</sup> Floor  
New York, NY 0004  
6/2016-6/2018

Chief Medical Officer

Vermillion, Inc  
12117 Bee Caves Rd  
Austin TX 78738  
9/2014-6/2016  
9/2014- 6/2016

Division Chief of Surgery  
Banner MD Anderson Cancer Center  
2946 E Banner Gateway Dr  
Gilbert, AZ 85235

6/2011-9/2014

Professor of Gynecologic Oncology  
The University of Texas MD Anderson Cancer Center  
1515 Holcombe Blvd  
Houston, TX 77030  
7/1995-6/2011

**EDUCATION****Degree-Granting Education**

University of Akron, Akron, OH, BS, 1982, Natural Sciences

Northeastern Ohio Universities College of Medicine, Rootstown, OH, MD, 1986, Biomedical Science

The University of Texas Health Science Center at Houston, Houston, TX, MS, 1993, Biomedical Sciences- Thesis, Characterization of two populations of the human ovarian cancer cell line, 2774, that express different levels of epidermal growth factor receptor.

**Postgraduate Training**

Residency, Obstetrics and Gynecology

U.T. Health Science Center at San Antonio, San Antonio, TX, Dr. Carl J. Pauerstein  
07/1986-06/1990

Fellowship, Gynecologic Surgery

University of Minnesota, Duluth, MN, Dr. Leo Twiggs  
07/1990-6/1991

Fellow, Gynecologic Oncology, Department of Biology The University of Texas MD Anderson Cancer Center, Houston, TX, Dr. J Taylor Wharton 07/91-06/93

Junior Faculty Associate, Gynecologic Oncology The University of Texas MD Anderson Cancer Center, Houston, TX, Dr. J. Taylor Wharton  
07/1993-06/1995

**CREDENTIALS**

Board Certification

American Board of Obstetrics and Gynecology, (Written Exam), 1990  
 American Board of Obstetrics and Gynecology: Special Qualification in Gynecologic Oncology, (Written Exam), 1996  
 American Board of Obstetrics and Gynecology, 1997  
 -Recertified 2022- 12/31/2023  
 American Board of Obstetrics and Gynecology: Special Qualification in Gynecologic Oncology, 2000  
 -Recertified 2022-12/31/2023

## **Licensures**

### **Active**

State of Arizona, AZ, 45110, 7/2011 – current  
 State of Indiana, IN 01074549B, 9/2014- current  
 State of Georgia, GA 173182 6/2014- present  
 State of Wisconsin 71734-20 9/5/2019-present  
 State of New York 307831 12/2020 to present  
 State of North Carolina 257141 2/13/2020 to present  
 State of Pennsylvania MD476656 1/31/2022 to present  
 State of Virginia 0101275018 4/27/2022 to present  
 State of Tennessee 66290 10/7/2022 to present  
 State of Minnesota 33916 1/1990-1/1993 and 4/18/23 to present

### **Inactive**

State of Kentucky- temporary license TP 106 9/6/22-4/1/2023  
 State of Texas, TX, H4856, 1988–8/2012

## **EXPERIENCE/SERVICE**

### **Academic Appointments**

Assistant Professor, Department of Gynecologic Oncology, Division of Surgery, The University of Texas M.D. Anderson Cancer Center, Houston, TX, 1995–1999  
 Assistant Professor, Department of Gynecologic Oncology, Division of Surgery, The University of Texas M.D. Anderson Cancer Center, Houston, TX, 1999–2002  
 Associate Professor, Department of Gynecologic Oncology, Division of Surgery, The University of Texas M.D. Anderson Cancer Center, Houston, TX, 2002–8/2008  
 Graduate Faculty, Biomedical Sciences, Graduate School of Biomedical Sciences, The University of Texas Houston Health Science Center, Houston, TX, 2003–2011  
 Associate Professor, Department of Gynecologic Oncology, Blanton Davis Ovarian Cancer Research Program, The University of Texas M. D. Anderson Cancer Center, Houston, TX, 2006–8/2008  
 Associate Director, Department of Gynecologic Oncology, Developmental Therapeutics, The University of Texas MD Anderson Cancer Center, Houston, TX, 2006–2011  
 Co-Division Director, Department of Gynecologic Oncology, Division of Surgery, Baylor College of Medicine, Houston, TX, 4/2006–4/2007

Professor, Department of Gynecologic Oncology, Blanton Davis Ovarian Cancer Research Program, The University of Texas MD Anderson Cancer Center, Houston, TX, 2008-2011

Associate Director, Department of Gynecologic Oncology, Developmental Therapeutics, The University of Texas MD Anderson Cancer Center, Houston, TX, 2011

Division Chief, Surgical Oncology, Banner MD Anderson Cancer Center, Gilbert, AZ 6/2011-9/2014

Vice Chair, Department of Oncology Services, Banner MD Anderson Cancer Center, Gilbert, AZ 6/2011-/9-2014

Adjunct Professor, Gynecologic Oncology, University of Texas, MD Anderson Cancer Center, Houston, Texas, 2012- 2014

Clinical Professor, Division of Clinical Education, Arizona College of Osteopathic Medicine, Midwestern University, Arizona, 2012- 2014

### **Administrative Appointments/Responsibilities**

**Assistant Program Director (Research)**, Fellowship in Gynecologic Oncology, Division of Surgery, The University of Texas M. D. Anderson Cancer Center, Houston, TX, 1999–2004

**Medical Director**, Community Relations, Department of Gynecologic Oncology, Division of Surgery, The University of Texas MD Anderson Cancer Center, Houston, TX, 4/2008–2011

### **Other Appointments/Responsibilities**

**Member**, Felix Rutledge Society, Houston, TX, 1995-Present  
 President, Felix Rutledge Society, 2008-2009

**Member**, Society of Gynecologic Oncologists, Chicago, IL, 1996–Present

**Member**, Quality and Outcomes Committee, Society of Gynecologic Oncology, 2012-Present

**Member**, Breakthrough Series; Improving Care at the End of Life, Houston, TX, 1997–2011

**Founder-Chairman**, Sprint for Life 5K Fun Run, M. D. Anderson Cancer Center, Houston, TX, 1998–Present

**Chairman**, Medical and Scientific Advisory Board, National Ovarian Cancer Coalition, Dallas, TX, 2003–Present

**President**, Houston Gynecologic & Obstetrics Society, Houston, TX, 2003–2004

**Treasurer**, Houston Gynecologic & Obstetrics Society, Houston, TX, 1998–2000

**Vice President**, Houston Gynecologic & Obstetrics Society, Houston, TX, 2001–

**Member**, Gynecologic Oncology Group, Philadelphia, PA, 2001–2011

**Departmental Liaison**, M D Anderson Cancer Center Women Faculty Programs, Houston, TX, 2/2010–2011

### **Endowed Positions**

N/A

**Consultantships**

N/A

**Military or Other Governmental Service**

N/A

**Institutional Committee Activities**

Medical Records Committee, Member, 1995–2011  
 Clinical Research Committee, Member, 1997–2000  
 Women's Faculty Administrative Organization Steering Committee, Member, 1998–1999  
 Cancer Committee, Hermann Hospital, Member, 1998–2001  
 Search Committee, Anesthesia, Member, 1999–2000  
 Ovarian SPORE Executive Committee, Member, 1999–2011  
 Student and Trainee Resources-Clinical Fellow's Research Award, Faculty Reviewer, 1999  
 Cancer Therapeutics Discovery Program Grants, Reviewer, 2000–2004  
 Clinical Research Committee, Member, 2001–2004  
 Search Committee, Internal Medicine, Member, 2001  
 Uterine SPORE Executive Committee, Member, 2003–2011  
 Faculty Promotion and Tenure Committee, Division of Surgery, Member, 2003–2011  
 Gynecologic Oncology Surgical Research Program (GO-SRP) Committee, Member, 2004–2011  
 Fellowship Planning Committee, Member, 2004–2011  
 Blanton-Davis Ovarian Cancer Research Program Executive Committee, Member, 2004–2011  
 Faculty Celebration Steering Committee, Member, 2004  
 Gynecologic Oncology Center for Surgical Research (GOCSR), Member, 2004  
 Ovarian Working Group, Department of Gynecologic Oncology, Chairman, 2005–2011  
 Search Committee, Department of Nephrology Chair, Member, 2005  
 Gynecologic Oncology T32 - Program Steering Committee, Member, 2005  
 The University of Texas M. D. Anderson Cancer Center, Gynecologic Oncology Group (GOG), Co-Principal Investigator, 2005–2011  
 Faculty Celebration Gala, Chairman, 2005  
 Faculty Leadership Committee, Member, 2006–2011  
 Executive Committee of Faculty Senate, Member, 2007–2009  
 Faculty Senate Committee, Chair Elect, 2010–2011  
 Faculty Senate Committee, Chair, 2011 – 2012  
 Faculty Senate Committee, Member, 2006–2011  
 Gynecologic Oncology Committee for New Institute of Personalized Cancer Therapy, Head, 4/2008–2011  
 Award Nomination Selection Committee, 2010–2011  
 Clinical Research Counsel, Member, 6/2008–2011  
 Clinical Research Committee, Member, 7/2009–2011  
 Women Faculty Programs, Member, 8/2009–2011  
 Charitable Activities Committee Subcommittee, Member, 2010–2011  
 OPPE/FPPE, Department Safety Officer, 2/2010–2011  
 Institutional Review Board 1 (IRB1), Associate Member, 8/2010–2011  
 Vice Chair, Department of Oncology Services, BMDACC, 2011- 2014  
 BMDACC Perioperative Logistic Committee, 2011- 2014  
 BMDACC Surgery Committee, 2011- 2014  
 BMDACC Phase II Steering Committee, 2011-2014  
 Relationship Committee between UT MD Anderson Cancer Center and BMDACC, 2011- 2014  
 BMDACC Research Faculty Guidance Committee, 2011- 2014  
 Banner Medical Group Knowledge Management Committee, 2012- 2014  
 BMDACC, Affiliate of UTMACC for Gynecologic Oncology Group (GOG), Principal Investigator, 2012- 2014  
 BMDACC Biospecimen Governance Committee Chair 2013- 2014  
 BMDACC Research Committee, Co-chair 03/2013- 2014  
 Banner Health Oncology Steering Committee, 5-9/2014

**HONORS AND AWARDS**

Medical Honor Society, Alpha Omega Alpha, 1986  
 Galloway Fellowship in Gynecologic Oncology, Memorial Sloan Kettering Cancer Center, 1989  
 Best Doctors in America®, 2005–2006, 2006–2007, 2007–2008, 2011, 2013

**RESEARCH****Grants and Contracts (past 5 years)****Funded**

Principal Investigator-MDACC, J. S. Blanton Research Fund, J. S. Blanton Research Fund, 1999–2011, \$116,367  
 Principal Investigator, 10%, Gene Developmental in Ovarian Cancer, Specialized Program of Research Excellence, 2001– 2011, \$50,000  
 Principal Investigator, Gene Therapy Development Award, W. M. Keck Center for Cancer Gene Therapy Development Award, 2001– 2011, \$50,000  
 Principal Investigator, Texas Federation of Business Professional Women Award, Texas Federation of Business Professional Women Award, 2001– 2011, \$6,337  
 Principal Investigator, The Ovarian Cancer Survivors Fund, Don-Ray George & Associates, 2003 – 2011, \$116,126  
 Co-Investigator, Efficacy and Mechanism of SERMs for Recurrent / Advanced Endometrial Cancer, Molecular Progression of Endometrial Cancer, P150CA098258, Specialized Program of Research Excellence, PI - Karen H. Lu, 9/1/2003 – 8/31/2008, \$992,019

Principal Investigator-MDACC, Gynecologic Oncology Center for Surgical Research (GOCSR), Houston Jewish Community Foundation, 2004 – 2011, \$50,000

Principal Investigator-MDACC, Susan G. Koch Ovarian Cancer Research Fund, Susan G. Koch, 2005 – 2011, \$50,000

Co-Investigator, The University of Texas M D Anderson Cancer Center, Gynecologic Oncology Group, Gynecologic Oncology Group, PI - Robert Coleman, M.D., 2005 – 2011.

**Pending**

N/A

**Other**

N/A

**Completed**

Principal Investigator, Evaluation of the Effect and Mechanism of Action of Adenovirus-mediated Tumor Suppressor Gene Therapy of Ovarian Cancer, Gynecologic Cancer Foundation, 1998–2006, \$25,000

Co-Investigator, Evaluating Fatigue and Other Symptoms of Ovarian cancer Patients with Ecological Momentary Assessment, Ovarian Cancer Research Development Award, PI - Karen Basen Engquist, Ph.D., 1999–2006, \$50,000

**Not Funded**

N/A

**Protocols**

**Funded**

Principal Investigator, Evaluating Fatigue and Other Symptoms of Ovarian Cancer Patients with Ecological Momentary Assessment, ID99-, 1999, Ovarian Cancer Research Development Award

Principal Investigator, A Phase II Study of Oral Xeloda Administered Twice Daily for Fourteen Days Every Three Weeks to Patients with Advanced Ovarian, Tubal or Peritoneal Cancer Refractory to Platinum and Taxanes, GYN 00-275, 2000–2001

Co-Principal Investigator, Phase II Evaluation of Oxaliplatin In Persistent or Recurrent Squamous Cell Carcinoma of the Cervix, GOG127P, PI - Charles Levenback, 2000–2003, GOG

Principal Investigator, A Phase 1 Dose Escalation Study of Intraperitoneal E1A Lipid Complex (1:3) with Combination Chemotherapy in Women with Epithelial Ovarian Cancer, ID 99-316, 2000–2006

Co-Principal Investigator, A Phase II Evaluation of Thalidomide (NSC #66847, IND #48832) In the Treatment of recurrent or Persistent Leiomyosarcoma of the Uterus, GOG231B, PI - Diane Bodurka, 2001–2002, GOG

Co-Principal Investigator, A Phase II Multicenter Study of Oral Xeloda Administered Twice Daily for Fourteen Days Every Three Weeks to Patients with Advanced or Recurrent Cervical Cancer, GYN01-080, PI - Lois Ramondetta, M.D., 2001–2003

Collaborator, A 2-Part Phase I/II Study of Extended Field External Irradiation and Intracavitary Brachytherapy combined with Chemo (Weekly Cisplatin-Arm 1) and Amifostine (Weekly Cisplatin and Amifostine-Arm 2), RTOG-C0116, PI - Anuja Jhingran, M.D., 2001– 2011, RTOG

Principal Investigator, A Phase I/II Study to Evaluate the Maximum Biologic Dose of Pegylated-Interferon (PEG- INTRON) in Patients with Platinum Resistant Ovarian, Peritoneal, or Fallopian Tube Cancer, ID02-115, 2002–2005, \$100,000, Integrated Therapeutics Group/Schering Plough

Collaborator, A Phase II Evaluation of Decetaxel and Gemcitabine Plus G-CSF in the treatment of recurrent of Persistent Leiomyosarcoma of the Uterus, GOG-0131G, PI - Lois Ramondetta, M.D., 2002–2005, GOG

Collaborator, A Phase II Evaluation of Liposomal Doxorubicin (Doxil) in the Treatment of Persistent or Recurrent Squamous Cell Carcinoma of the Cervix, GOG 127-R, PI - Diane Bodurka, M.D., 2002–2005, GOG

Co-Principal Investigator, Phase II Study of Irofulven (IND #48914) in Patients with Refractory or Recurrent Advanced Epithelial Ovarian Cancer Using Every-Other-Week Dosing, GYN01-486, PI - Diane Bodurka, 2002–2005

Collaborator, A Phase II Evaluation of Capecitabine (NSC#712807) in the Treatment of Persistent or Recurrent Non-squamous Cell Carcinoma of the Cervix, GOG-0128G, PI - Diane Bodurka, M.D., 2002– 2011, GOG

Collaborator, Treatment of Patients with Stage IB2 Carcinoma of the Cervix: A Randomized Comparison of Radical Hysterectomy and Tailored Chemo-Radiation versus Chemo-radiation, GOG0201, PI - Charles Levenback, M.D., 2003–2005, GOG

Collaborator, A Randomized Study of Tamoxifen versus Thalidomide (NSC no.66847) in Patients with Biochemical-Recurrence- Only Epithelial Ovarian Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma after First-Line Chemotherapy, GOG-0198, PI - Robert Coleman, M.D., 2003–2006, GOG

Collaborator, A Phase I/II Study of COX-2 Inhibitor, Celebrex (Celecoxib), and Chemoradiation in Patients with Locally Advanced Cervical Cancer, RTOG-C0128, PI - Patricia Eifel, M.D., 2003–2011, RTOG

Principal Investigator, A Phase I/II Study of Gleevec/Taxol in Patients with Newly Diagnosed Stage IIIC or IV or Recurrent (any stage) Uterine Papillary Serous Carcinoma (UPSC), GYN03-0177, 2003–2011, Novartis

Collaborator, A Phase III Clinical Trial of Tisseel VH Fibrin Sealant to Reduce Lymphedema Incidence after Inguinal Lymph Node Dissection Performed in the Management of Vulvar Malignancies, GOG195, PI - Pedro Ramirez, M.D., 2003–2011, GOG

Collaborator, A Phase III Randomized Clinic Trial of Laparoscopic Pelvic & Para-Aortic Node Sampling with Vaginal Hysterectomy and BSO versus Open Laparotomy with Pelvic and Para-Aortic Node Sampling and Abdominal Hysterectomy and BSO in Endometrial

Adenocarcinoma and Uterine Sarcoma, GOG-LAP2, PI - Pedro Ramirez, M.D., 2003–2011, GOG

Collaborator, A Phase III Randomized Trial of Paclitaxel and Carboplatin versus Triplet or Sequential Doublet Combinations in Patients with Epithelial Ovarian or Primary Peritoneal Cancer, GOG-0182, PI - John Kavanagh, M.D., 2003–2011, GOG

Collaborator, A Randomized Phase III Study of Paclitaxel plus Cisplatin versus Vinorelbine Plus Cisplatin versus Gemcitabine Plus Cisplatin versus Topotecan Plus Cisplatin in Stage IVB, Recurrent or Persistent Carcinoma of the Cervix, GOG-0204, PI - Charles Levenback, M.D., 2003–2011, GOG

Principal Investigator, Phase I/II Study of Weekly Topotecan and Iressa in Patients with Platinum-Resistant Ovarian/Peritoneal/Fallopian Tube Cancer, 2003-0322, 2004–2007, \$92,500, GlaxoSmithKline/Astra Zeneca

Principal Investigator, A Phase I/II Randomized Study of Intraperitoneal tDCC-E1A and Intravenous Paclitaxel in Women with Platinum-Resistant Ovarian Cancer, ID02-321, 2004–2011, \$365,000, Marcus Foundation Funds-UT M. D. Anderson Cancer Center

Principal Investigator, A Phase II Study of RAD001 in Patients with Recurrent Endometrial Cancer, 2004-0002 IND 69277, 2004–2011, \$111,300, Novartis

Collaborator, A Randomized, Phase II Trial of Doxorubicin/Cisplatin/Paclitaxel and G-CSF versus Carboplatin/Paclitaxel in Patients with Stage III and IV or Recurrent Endometrial Cancer, GOG-0209, PI - Lois Ramondetta, M.D., 2004–2011, GOG

Mentor, Training Grant - Department of Gynecologic Oncology, Training of Academic Gynecologic Oncologists, NIH/NCI, 1 T32CA101642-01A, PI - David M. Gershenson, MD, 2005–2010, \$1,535,549 (\$181,757/year), NIH/NCI

Collaborator, A Limited Access Phase II Trial of Cetuximab (C225, NSC 714692) in Combination with Cisplatin (NSC #119875) in the Treatment of Advanced, Persistent, or Recurrent Carcinoma of the Cervix, GOG-0076DD, PI - Robert Coleman, M.D., 2005–2011, GOG

Principal Investigator, A Phase I Trial of Tailored Radiation Therapy with Concomitant Cetuximab (C225, NSC# 714692) and Cisplatin (NSC# 119875) in the Treatment of Patients with Cervical Cancer, GOG-9918, 2005–2011, GOG  
 Collaborator, A Phase II Evaluation of Pemetrexed (Alimta, LY231514, IND #40061) in the Treatment of Recurrent Carcinoma of the Cervix, GOG-0127T, PI - Charles Levenback, M.D., 2005–2011, GOG  
 Collaborator, A Phase II Evaluation of Thalidomide (NSC# 66847, IND# 48832) In The Treatment Of Recurrent Or Persistent Carcinosarcoma of the Uterus, GOG-0230B, PI - Lois Ramondetta, M.D., 2006–2007, GOG  
 Principal Investigator, A Dose-Escalating Phase I Study with an Expanded Cohort to Assess Feasibility of Intraperitoneal Carboplatin & Intravenous Paclitaxel in Patients with Previously Untreated Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer, GOG-9917, 2006–2011, GOG  
 Collaborator, A Phase II Evaluation of Pemetrexed (Alimta, LY231514, IND #40061) in the Treatment of Recurrent or Persistent Platinum-Resistant Ovarian or Primary Peritoneal Carcinoma, GOG-0126Q, PI - Siqing Fu, M.D., 2006–2011, GOG  
 Co-Principal Investigator, A Phase II Study of Faslodex in Recurrent/Metastatic Endometrial Carcinoma, GOG-0188, PI - Lois Ramondetta, M.D., 2006–2011, GOG  
 Co-Principal Investigator, Phase III Carboplatin & Paclitaxel + Placebo vs. Carboplatin & Paclitaxel + Concurrent Bevacizumab (NSC #704865, IND # 7921) follow by Placebo, vs Carboplatin & Paclitaxel + Concurrent & Ext Bevacizumab, in Advanced Stage Epithelial Ovarian & Peritoneal Primary Cancer, GOG-0218, PI - Robert Coleman, M.D., 2006–2011, GOG  
 Collaborator, A Phase II Evaluation of ABI-007 (IND #55,974) in the Treatment of Persistent or Recurrent Squamous or Non Squamous Cell Carcinoma of the Cervix (Abraxis BioScience, Inc. Study #CA026) (Group B), GOG-0127V, PI - Robert Coleman, M.D., 2007–2011, GOG  
 Principal Investigator, Preliminary Evaluation of Femara (Letrozole) for Adjuvant Treatment After Completion of First-Line Chemotherapy for Patients with Optimally Debulked and Chemoresponsive Ovarian Cancer, IRB 2006-0689, 2007–2011, \$314,989

Principal Investigator, Randomized Phase 2 Study of MLN8237, an Aurora A Kinase Inhibitor, Plus Weekly Paclitaxel or Weekly Paclitaxel Alone in Patients with Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Preceded by a Phase 1 Portion in Patients with Ovarian or Breast Cancer, Millennium.

#### Unfunded

Collaborator, A Phase II Study of Intravenously Administered Tirapazamine Plus Cisplatin in Subjects with Cervical Cancer, GYN96-136, PI - Charles Levenback, M.D., 1996–2004  
 Principal Investigator, Phase I Study of recurrent ovarian cancer Adp53, ID 97-288, 1997  
 Collaborator, Telomerase Testing in Peritoneal Washings from Ovarian Cancer Patients Undergoing Second Look Laparotomy, LAB98-080, PI - David Gershenson, M.D., 1998–2005  
 Collaborator, A Pilot Study of Transfusion of rhTPO-Derived Autologous Platelets Cryopreserved with Thromobosol and 2% DMSO in Patients with Gynecologic Malignancy Receiving Carboplatin, GYN97-310, PI - Saroj Vadhan, 1999–2004  
 Collaborator, Paclitaxel, Carboplatin, and Herceptin for Patients with Untreated Advanced, (Cohort A) or Recurrent Platinum-Sensitive (Cohort B) Epithelial Ovarian Cancer, Peritoneal Cancer, or Fallopian Tube Cancer, GYN99-067, PI - David Gershenson, M.D., 1999–2004  
 Collaborator, Paclitaxel, Carboplatin, and Herceptin for Patients with Untreated Advanced Epithelial Ovarian Cancer, Peritoneal Cancer, or Fallopian Tube Cancer, GYN99-132, PI - David Gershenson, M.D., 1999–2007  
 Collaborator, Feasibility of Measuring Gene Expression Patterns Using Tissue Acquisition of Primary Stage III and IV Epithelial Ovarian Cancer, Fallopian Tube, or Primary Peritoneal Cancer and Gene Expression Array Technology for Predicting Paclitaxel Chemotherapy Sensitivity and Resistance, ID00-408, PI - David Gershenson, M.D., 2000–2011  
 Principal Investigator, Phase II Study of Paclitaxel for Ovarian Stromal Tumors as First-Line or Second-Line Therapy, GOG-0187, 2000  
 Collaborator, A Phase II Study of Intraperitoneal E1A-Lipid complex for Patients with Advanced Epithelial Ovarian CX without Her-2/Neu Overexpression, ID00-306, PI - Naoto Ueno, 2001–2002  
 Collaborator, Phase II Study of Intraperitoneal Recombinant Human Interleukin-12 (RHIL-12) in Patients with Peritoneal Carcinomatosis (Residual Disease <1cm) Associated with Ovarian epithelial CX or Primary Peritoneal Carcinoma, ID00-232, PI - Renato Lenzi, 2001–2005  
 Collaborator, Feasibility Study of Intraoperative Lymphatic Mapping and Sentinel Lymph Node Identification in Patients with Endometrial Cancer, ID01-290, PI - Diane Bodurka, M.D., 2001–2006  
 Collaborator, A Phase II Multicenter Trial of Paclitaxel and Carboplatin in Women with Advanced (IIb, IIc, IVa and IVb) or Recurrent (All Stages) Mixed Malignant Mullerian Tumors (MMMT) of the Uterus, ID01-229, PI - Lois Ramondetta, M.D., 2001–2011  
 Collaborator, A Phase II Study: Paclitaxel and Pelvic Radiation for Stage I-IIIA Papillary Serous Carcinoma of the Endometrium, ID-418, PI - Anuja Jhingran, 2001–2011  
 Collaborator, Chemotherapy-Related Toxicities in Ovarian Cancer Patients: Preference Assessments of Patients, Family Members, Ancillary Staff and Gynecologic Oncologists, and Patients' Quality of Life, GYN00-409, PI - Diane Bodurka, M.D., 2001–2011  
 Collaborator, Clinical and Molecular Genetic Determinants of Late Complication in Patients Treated with Radiation Therapy for Cervical Cancer, LAB01-380, PI - Patricia Eifel, M.D., 2001–2011  
 Collaborator, Evaluating Fatigue and Other Symptoms of Ovarian Cancer Patients with Ecological Momentary Assessment, ID00-013, PI - Karen Basen-Engquist, 2001–2011  
 Collaborator, Phase II Study of Mifepristone (RU-486) in the Treatment of PR Positive Advanced/Recurrent Endometrial Adenocarcinoma and Low Grade Endometrial Stromal Sarcoma (LGESS), ID01-212, PI - Lois Ramondetta, M.D., 2001–2011  
 Collaborator, Use of the CA125 Algorithm for the Early Detection of Ovarian Cancer in Low Risk Women, ID01-022, PI - Karen Lu, 2001–2011  
 Co-Principal Investigator, Vacuum-Assisted Closure in the treatment of Gynecologic Oncology Wound Failures, RCR01-156, PI - Pedro Ramirez, 2002–2003  
 Collaborator, Phase I Trial of Concurrent Weekly CPT-11, Cisplatin, and Radiotherapy for Patients with Newly Diagnosed Stage IIb-IVa Cancer of the Uterine Cervix, ID02-526, PI - Pedro Ramirez, M.D., 2002–2005  
 Collaborator, A Phase II Study of Chemoimmunotherapy for Patients with Potentially Platinum Sensitive Müllerian (Epithelial Ovarian, Peritoneal, or Fallopian Tube) Carcinomas, ID02-231, PI - Ralph Freedman, M.D., Ph.D., 2002–2011  
 Collaborator, A Prevalence Study of HNPCC Gene Mutation in Women with Endometrial Cancers, ID01-533, PI - Karen Lu, M.D., 2002–2011  
 Collaborator, Feasibility of Measuring Gene Expression Patterns Using Tissue Acquisition of Primary Peritoneal CX and Gene Expression Array Technology for Predicting Paclitaxel Chemo Sensitive and Resistant, ID00-408, PI - David M. Gershenson, M.D., 2002–2011  
 Collaborator, Modulation of Putative Surrogate Endpoint Biomarkers in Endometrial Biopsies from Women with HNPCC, ID01-340, PI - Karen Lu, M.D., 2002–2011  
 Collaborator, The Utility and Impact of Computed Tomography and Serum CA-125 in the Management of Newly Diagnosed Ovarian Cancer, ID02-143, PI - Pedro Ramirez, M.D., 2002–2011



Co-Principal Investigator, Evaluation of Molecular Markers in Malignant Mixed Mesodermal Tumors (MMMT) of the Ovary, LAB03-0653, PI - Lois Ramondetta, M.D., 2003-2005

Co-Principal Investigator, A Phase I Study Evaluating the Safety and Tolerability of PS-341(Bortezomib) and Carboplatin in Patients with Platinum Resistant Recurrent Ovarian Cancer, Primary Peritoneal Cancer, and Fallopian Tube Cancer, ID02-114, PI - Pedro Ramirez, 2003-2007

Collaborator, Phase III Randomized Study of TLK286 Versus Doxil/Caelyx or Hycamtin as Third-Line Therapy in Platinum Refractory or Resistant Ovarian Cancer, ID03-184, PI - John Kavanagh, M.D., 2003-2007

Co-Principal Investigator, Role of Secondary Cytoreductive Surgery for Recurrent Ovarian: A 20-Year Experience, RCR03-0803, PI - Pedro Ramirez, 2003-2007

Collaborator, A Phase II Study Evaluating the Utility of Letrozole in the Treatment of Recurrent, Estrogen Receptor (ER) Positive, Epithelial Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer, ID02-698, PI - Pedro Ramirez, M.D., 2003-2011

Collaborator, A Pilot Study of Laparoscopic Extraperitoneal Lymph Node Dissection in Patients with Locally Advanced Cervical Cancer, ID03-0098, PI - Pedro Ramirez, M.D., 2003-2011

Collaborator, Phase 1-2a Dose-Ranging Study of TLK286 in Combination with Doxil in Platinum Refractory or Resistant Ovarian Cancer, ID02-571, PI - John Kavanagh, M.D., 2003-2011

Collaborator, Phase II Study of Letrozole in Patients with Recurrent Advanced Borderline Tumors or Low Grade Epithelial Cancers of the Ovary, Fallopian Tube and Primary Peritoneum, 2003-0486, PI - John Kavanagh, M.D., 2003-2011

Collaborator, Quality of Life and Preferences of Ovarian Cancer Patients Enrolled on a Randomized Trial of High-Dose versus Conventional Dose Chemotherapy, ID02-680, PI - Charlotte Sun, Ph.D., 2003-2011

Co-Principal Investigator, A Phase II Study of Gemcitabine and Cisplatin for Advanced or Recurrent Endometrial Cancer, 2003-0823, PI - Jubilee Brown, M. D., 2004-2011

Collaborator, Chemoradiation-Induced Nausea and Emesis: A Prospective Study to Assess Patient Preferences and Quality of Life, 200-0529, PI - Charlotte Sun, Ph.D., 2004-2011

Collaborator, The Role of Appendectomy at the Time of Tumor Reductive Surgery in Patients with Epithelial Ovarian Cancer, RCR05-0630, PI - Pedro Ramirez, M.D., 2005

Collaborator, Total Laparoscopic Radical Hysterectomy: Outcomes Evaluation, RCR05-0390, PI - Pedro Ramirez, M.D., 2005-2007

Co-Principal Investigator, A Pilot Clinical Trial with Molecular Marker Study of Chemosensitization to Carboplatin by Use of Vidaza in Platinum Resistant or Refractory Epithelial Ovarian Cancer, 2005-0009, PI - Siqing Fu, M.D., 2005-2011

Collaborator, Evaluation of Demographics and Perioperative Care of Patients Undergoing Laparoscopic Surgery for Gynecologic Malignancies: A 15-Year Experience, RCR05-0137, PI - Pedro Ramirez, M.D., 2005-2011

Collaborator, Systemic Antineoplastic Therapy in Ovarian Cancer Patients with Renal Dysfunction, RCR05-0707, PI - John Kavanagh, M.D., 2005-2011

Collaborator, A Phase I Dose Escalation Study of ABI-007 with Carboplatin as First-Line Therapy in Patients with Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma, 2006-0405, PI - Robert Coleman, M.D., 2006-2011

Principal Investigator, Phase II Study of Cetuximab (Erbix) in Patients with Progressive or recurrent Endometrial Cancer, 2006-0211, 2006-2011

Collaborator, A Multi-Institutional Study of Proteomic Evaluation of Epithelial Ovarian Cancer, Primary Peritoneal Cancer, and Fallopian Tube Cancer Patients in First Clinical Remission: Development of a Protein Fingerprint Profile of Relapse, 2005-0780, PI - Karen Lu, M.D., 2007-2011

Co-Principal Investigator, A Phase II, Open-Label, Non-Comparative, International, MC Study to Assess the Efficacy and Safety of KU-0059436 Given Orally Twice Daily in Patients with Advanced BRCA1-or BRCA2-Associated Ovarian Cancer, 2007-0098, PI - Karen H. Lu, M.D., 2007-2011

Collaborator, A Study of the Efficacy of MORAb-003 in Subjects with Platinum-Sensitive Epithelial Ovarian Cancer in First Relapse, 2006-0889, PI - Robert Coleman, M.D., 2007-2011

Collaborator, Phase I/II and Pharmacokinetic Study of Docetaxel Plus VEGF Trap (AVE0005, NSC #724770) In Patients with Recurrent Ovarian, Primary Peritoneal, and Fallopian Tube Cancer, 2006-0329, PI - Robert Coleman, M.D., 2007-2011

## **Patents and Technology Licenses**

### **Patents**

N/A

### **Technology Licenses**

N/A

### **Grant Reviewer/Service on Study Sections**

Review Committee on NIH CTRC, NIH, Member, Louisiana State University, 1997

AD HOC on NCI P01, NCI, Ad Hoc Member, Tulane University Health Science Center, 2004

Clinical Research Review Committee NCI, NCI, Member, Mayo Clinic, 2004

NIH-CONC Clinical Oncology Study Section Review (R01, R21), NIH, Member, Clinical Oncology Study Section Review (R01, R21), San Francisco, CA, 2004

Review Committee NCI-NIH, NIH, Member, Duke Comprehensive Cancer Center, Duke University, 2004

Review Committee on NCI-I Career Awards, NCI, Member, 2004

NCI PO1 Cluster Review, NIH, Member, Bethesda, MD, 2005

NIH-CONC Clinical Oncology Study Section Review (R01, R21), NIH, Member, Clinical Oncology Study Section Review (R01, R21), Bethesda, MD, 2005

Review Committee NCI-NIH, PO1 Experimental Therapeutics II Cluster Review, NIH, Member, PO1 Experimental Therapeutics II Cluster Review, Rockville, MD, 2005

## **PUBLICATIONS**

### **Peer-Reviewed Original Research Articles**

1. Yu D, **Wolf JK**, Scanlon M, Price JE, Hung MC. Enhanced c-erbB-2/neu expression in human ovarian cancer cells correlates with more severe malignancy that can be suppressed by E1A. *Cancer Res* 1993 Feb 15;53(4):891-8.
2. Hamada K, Zhang WW, Alemany R, Roth JA, **Wolf JK**, Mitchell MF. Gene therapy of cervical cancer by adenovirus-mediated p53 gene transfer. *J Cell Biochem Suppl* 1995; 21A:421.
3. Gershenson DM, Morris M, Burke TW, Levenback C, **Wolf JK**, Warner D, Matthews CM, Wharton JT. Treatment of poor-prognosis sex cord-stromal tumors of the ovary with the combination of bleomycin, etoposide, and cisplatin(BEP). *Obstet Gynecol* 1996 Apr;87(4):527-31.

4. **Wolf JK**, Levenback C, Malpica A, Morris M, Burke T, Mitchell MF. Adenocarcinoma in situ of the cervix: significance of cone biopsy margins. *Obstet Gynecol* 1996 Jul; 88(1)(1):82-6.
5. Levenback C, Morris M, Burke TW, Gershenson DM, **Wolf JK**, Wharton JT. Groin dissection practices among gynecologic oncologists treating early vulvar cancer. *Gynecol Oncol* 1996 Jul; 62(1)(1):73-7.
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7. Mitchell MF, Hamada K, Jagannadha S, Satterfield WC, Buchholz S, **Wolf JK**, Zhang WU, Alemany R, Tortolero-Luna G, Keeling ME, Wharton JT, Roth JR. Transgene expression in the rhesus cervix mediated by an adenovirus expressing b-galactosidase. *Am J Obstet Gynecol* 1996;174:1094-1101.
8. Brader KR, **Wolf JK**, Hung MC, Yu D, Crispens MA, van Golen KL, Price JE. Adenovirus E1A expression enhances the sensitivity of an ovarian cancer cell line to multiple cytotoxic agents through an apoptotic mechanism. *Clin Cancer Res* 1997 Nov; 3(11):2017-24.
9. Gershenson DM, Silva EG, Levy L, Burke TW, **Wolf JK**, Tornos C. Ovarian serous borderline tumors with invasive peritoneal implants. *Cancer* 1998 Mar; 82(6)(6):1096-103.
10. Brader KR, **Wolf JK**, Chakrabarty S, Price JE. Epidermal growth factor receptor (EGFR) antisense transfection reduces the expression of EGFR and suppresses the malignant phenotype of a human ovarian cancer cell line. *Oncol Rep* 1998 Sep-Oct; 5(5):1269-74.
11. Price JE, **Wolf JK**, Pathak S. Distinctive karyotypes and growth patterns in nude mice reveal cross-contamination in an established human cancer cell line. *Oncol Rep* 1998 Jan-Feb; 5(1)(1):261-6.
12. **Wolf JK**, Kim TE, Fightmaster D, Bodurka D, Gershenson DM, Mills G, Wharton JT. Growth suppression of human ovarian cancer cell lines by the introduction of a p16 gene via a recombinant adenovirus. *Gynecol Oncol* 1999 Apr; 73(1)(1):27-34.
13. **Wolf JK**, Mullen J, Eifel PJ, Burke TW, Levenback C, Gershenson DM. Radiation treatment of advanced or recurrent granulosa cell tumor of the ovary. *Gynecol Oncol* 1999 Apr; 73(1):35-41.
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18. Parker LP, **Wolf JK**, Price JE. Adenoviral-mediated gene therapy with Ad5CMVp53 and Ad5CMVp21 in combination with standard therapies in human breast cancer cell lines. *Ann Clin Lab Sci* 2000 Oct; 30(4)(4):395-405.
19. Gordinier ME, Ramondetta LM, Parker LP, **Wolf JK**, Follen M, Gershenson DM, Bodurka-Bervers D. Survey of female gynecologic oncologists and fellows: balancing professional and personal life. *Gynecol Oncol* 2000 Nov; 79(2)(2):309-14.
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84. Fu S, Hu W, Iyer R, Kavanagh JJ, Coleman RL, Levenback CF, Sood AK, **Wolf JK**, Gershenson DM, Markman M, Hennessy BT, Kurzrock R, Bast RC. Phase 1b-2a study to reverse platinum resistance through use of a hypomethylating agent, azacitidine, in patients with platinum-resistant or platinum-refractory epithelial ovarian cancer. *Cancer*. 2011 Apr 15:117(8) e-Pub 2010 Nov 8.
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89. King ER, Tung CS, Tsang YT, Zu Z, Lok GT, Deaves MT, Malpica A, **Wolf JK**, Lu KH, Birrer MJ, Mok SC, Gershenson DM, Wong KK. The anterior gradient homolog 3 (AGR3) gene is associated with differentiation and survival in ovarian cancer. *American Journal of Surgical Pathology*, 2011 Jun, 35(6):904-12.
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91. Fu S, Hennessy BT, Ng CS, Ju Z, Coombes KR, **Wolf JK**, Sood AK, Levenback CF, Coleman RL, Kavanagh JJ, Gershenson DM, Markman M, Dice K, Howard A, Li J, Li Y, Stemke-Hale K, Dyer M, Atkinson E, Jackson E, Kundra V, Kurzrock R, Bast RC Jr, Mills GB. Perifosine plus docetaxel in patients with platinum and taxane resistant or refractory high-grade epithelial ovarian cancer. *Gynecol Oncol*. 2012 Jul;126(1):47-53.
92. Julius JM, Tanyi JL, Ramos L, Munsell MF, Watkins JL, Coleman RL, **Wolf JK**, Smith JA. Evaluation of pegylated liposomal doxorubicin dose on the adverse drug event profile and outcomes in treatment of recurrent endometrial cancer. *International Journal of Gynecologic Oncology*. 2013 Feb;23(2):348-54
93. Estrella JS, **Wolf JK**, Deavers MT. Ovarian serous carcinoma associated with a distinct "corded and hyalinized" pattern. *Archives of Pathology and Laboratory Medicine*. 2013 Feb;137(2):275-9.
94. Julius JM, Nogueras-Gonzalez GM, Watkins JL, Coleman RL, **Wolf JK**, Smith JA. Effect of declining renal function on the incidence of adverse drug events associated with liposomal doxorubicin in patients treated for gynecologic malignancies. *International Journal of Gynecologic Oncology*. 2013 Feb;23(2):48-54.
95. Robert L. Coleman, MD; Thomas J. Herzog, MD; Daniel W. Chan, PhD; Donald G. Munroe, PhD; Todd C. Pappas, PhD; Alan Smith, MS; Zhen Zhang, PhD; Judith Wolf, MD. Validation of a second-generation multivariate index assay for malignancy risk of adnexal masses. *Am J Obstet Gynecol* 2016A
96. The clinical utility of an elevated-risk multivariate index assay score in ovarian cancer patients. Eskander RN, [Carpenter BA](#), [Wu HG](#), [Wolf JK](#) *Curr Med Res Opin*. 2016
97. Noninvasive Blood-based Combinatorial Proteomic Biomarker Assay to Detect Breast Cancer in Women over age 50 with BI-RADS 3, 4, or 5 Assessment. Henderson MC, [Silver M1](#), [Tran Q1](#), [Letsios EE1](#), [Mulpuri R2](#), [Reese DE1](#), [Lourenco AP3](#), [LaBaer J4](#), [Anderson KS4](#), [Alpers J5](#), [Costantini C6](#), [Rohatgi N7](#), [Ali H8](#), [Baker K9](#), [Northfelt DW10](#), [Ghosh K11](#), [Grobmyer SR12](#), [Polen W13](#), [Wolf JK1](#). *Clin Cancer Res*. 2019
98. Breast density does not impact the ability of Videssa® Breast to detect breast cancer in women under age 50. [Reese DE1](#), [Henderson MC1](#), [Silver M1](#), [Mulpuri R1](#), [Letsios E1](#), [Tran Q1](#), [Wolf JK1](#). *PLoS One*. 2017.
99. Editors note: Therapeutic Targeting of ATP7B in Ovarian Carcinoma. Mandala LS, Zuzi V., Schmandt R, Leshane ES, Halder JB, Armaniz-Peña GN, Spannuth WA, Tanaka T, Shahzad MMK, Lin YG, Nick AM, Danes CG, Lee JW, Jennings NB, Vivas-Mejia PE, Wolf JK, Coleman RL, Siddik ZH, Lopez-Berenstein G, Lutsenko S, Sood AK. *Clin Cancer Res*. 2021 Aug 1;27 (15):4454. doi: 10.1158/1078-0432.CCR-21-2120. PMID: 34341059. No abstract available.

#### Invited Articles

1. **Wolf JK**, Wharton JT. Wild-type p53 overexpression: what role in tumorigenesis? *Gynecol Oncol* 60(3):337-8, 3/1996.
2. **Wolf JK**. Management of wound complications. *Clin Consults in Ob/Gyn* 8:79-84, 1996.
3. **Wolf JK**, Ramirez PT. The molecular biology of cervical cancer. *Cancer Invest* 19(6)(6):621-9, 2001.
4. **Wolf JK**, Jenkins AD. Gene therapy for ovarian cancer (review). *Int J Oncol* 21(3)(3):461-8, 9/2002.
5. **Wolf JK**, Coleman RL. Commentary on, Phase I trial of intraperitoneal injection of the E1B-55-kd-gene-deleted adenovirus ONYZ-015(d11520) given on days 1 through 5 every 3 weeks in patients with recurrent/refractory epithelial ovarian cancer. Vasey, et al. *J Clin Oncol* 2002;20:1562-9." *Women's Oncol Rev* 2:325-7, 2002.
6. **Wolf JK**, Franco EL, Arbeit JM, Shroyer KR, Wu TC, Runowicz CD, Tortolero-Luna G, Herrero R, Crum CP. Innovations in understanding the biology of cervical cancer. *Cancer S* 98(9):2064-9, 2003.
7. **Wolf JK**, Franco EL, Arbeit JM, Shroyer KR, Wu TC, Runowicz CD, Tortolero-Luna G, Herrero R, Crum CP. Innovations in understanding the biology of cervical cancer. *Cancer S* 98(9)(9 Suppl):2064-9, 2003.
8. Markman, Gershenson DM, **Wolf JK**. Controversies in Ovarian Cancer. *ACOG Update* 30:1-9, 2004.
9. Soliman PT, Slomovitz BM, **Wolf JK**. Mechanisms of cervical cancer. *Drug Discov Today: Dis Mech* 1(2):253-258, 2004.
10. Slomovitz B, Soliman P, **Wolf JK**. New standards for treating recurrent ovarian cancer. *NOCC* 19(Summer):5, 2004.
11. **Wolf JK**, Slomovitz BM. Novel biologic therapies for the treatment of endometrial cancer. *Int J Gynecol Cancer* 15(2):411, 2005.
12. **Wolf JK**. Prevention and treatment of vaginal stenosis resulting from pelvic radiation therapy. *Community Oncol* 3(10):665-71, 2006.

#### Editorials

1. **Wolf JK**, Wharton JT. Wild-type p53 overexpression: what role in tumorigenesis? *Gynecol Oncol* 60(3):337-8, 1996.

#### Other Articles

1. **Wolf JK**. Gynecologic Cancer Treatment Update (Highlights from ASCO 2003). *Vital Signs Monograph*, Fall, 2003.
2. Herzog, Coleman R, McGuire, Monk B, Spriggs D, **Wolf JK**. Patterns of Practice in Selected Gynecologic Malignancies. Colloquium at the Annual Meeting on Women's Cancer 2005 36th Annual Meeting of the Society of Gynecologic Oncologist . (SGO Monograph), 2005.

#### Book Chapters

1. Hallum AV, III, Coleman RL, **Wolf JK**. Gynecologic Oncology. In: The M. D. Anderson Surgical Oncology Handbook. Ed(s) David H. Berger, Barry W. Feig, and George M. Fuhrman. Little Brown and Company: Boston, MA, 326-368, 1995.
2. Bevers MW, Bodurka Bevers DC, **Wolf JK**. Gynecologic Cancers. In: The M. D. Anderson Surgical Oncology Handbook, Second Edition. Ed(s) Barry W. Feig, David H Berger, and George M. Fuhrman. Lippincott Williams & Wilkins: Philadelphia, 377-424, 1998.
3. **Wolf JK**, Mills GB, Bast RC, et al. P53-mediated Gene Therapy. In: Ovarian Cancer. Ed(s) Frank Shart, Tony Blackett, Jonathan Berek and Robert Bast. Isis Medical Media Ltd: Oxford England, 259-27, 1998.
4. **Wolf JK**, Burke TW. Vulva/Vaginal Cancer. In: Practical Strategies in Obstetrics and Gynecology. Ed(s) Mitchell P. Dombrowski, S. Gene McNeeley, Kamran S. Moghissi, and Adnan R. Munkarah. W. B. Saunders Company: Philadelphia, 449-457, 2000.
5. **Wolf JK**. Molecular Biology. In: ACS Atlas of Clinical Oncology: Cancer of the Female Lower Genital Tract. Ed(s) Eifel PJ, Levenback C. B.C. Decker, Inc: Hamilton London, 2001.
6. Bevers MW, Bodurka Bevers DC, **Wolf JK**. Gynecologic Cancers. In: The M. D. Anderson Surgical Oncology Handbook, Third Edition. Ed(s) Barry W. Feig, David H. Berger, and George M. Fuhrman. Lippincott Williams & Wilkins: Philadelphia, PA, 445-490, 2003.
7. Tanyi JL, Crotzer D, **Wolf JK**, Yu S, Hasegawa Y, Lahad J, Wa Cheng K, Umez-Goto M, Prestwich GD, Morris A, Newman RA, Felix EA, Lapis GB, Mills GB. Lysophosphatidic Acid as a Targets for the Molecular Diagnosis and Therapy of Ovarian Cancer. A Review Article. In: Functional Lipidomics. Ed(s) Feng L, Prestwich GD. CRC Press Taylor & Francis Group: Boca Raton, FL, 101-123, 2005.

8. **Wolf JK**, Wharton JT. Surgery for Ovarian Cancer. In: Gynecologic Cancer. Ed(s) Gershenson DM, Eifel PJ, Kavanagh JJ, and Silva E. Springer-Verlag: New York, NY, 174-186, 2005.
9. Slomovitz BM, Soliman PT, **Wolf JK**. Gynecologic Cancers. In: The M. D. Anderson Surgical Oncology Handbook, Fourth Edition. Ed(s) Barry W. Feig, David H. Berger, and George M. Fuhrman. Lippencott Williams & Wilkins: Philadelphia, PA, 520-563, 2006.
10. Smith JA, **Wolf JK**. Ovarian Cancer. In: Pharmacotherapy: A Pathophysiologic Approach 8th Edition, 8th. Ed(s) DiPiro JT, Matzke GR, Yee GC, Talbert RL, Wells BG, Posey LM. McGraw-Hill Companies: Illinois. 2010.

**Letters to the Editor**

N/A

**Manuals, Teaching Aids, Other Teaching Publications**

N/A

**Other Publications**

N/A

**EDITORIAL AND REVIEW ACTIVITIES****Editor/Service on Editorial Board(s)**

N/A

**Member of Editorial Review Board**

Editorial Board Member, Clinical Ovarian Cancer: &amp; Other Gynecologic Malignancies, CIG Media, 2008–present

Editorial Board Reviewer, European Journal of Clinical and Medical Oncology, San Lucas Medical Limited c/o Barefoot Investment Ltd,

Editorial Board of the Peer Reviewed Journal, 2010–present

Editorial Board Reviewer, American Society of Clinical Oncology, 2013 ASCO Educational Book

Editorial Advisory Board Reviewer, ADC Review/Journal of Antibody-drug Conjugates, 2013

**Journal Reviewer**

Reviewer, Gynecologic Oncology, 1995–present

Adhoc Reviewer, Obstetrics and Gynecology, 1996–present

Adhoc Reviewer, Clinical Cancer Research, 1998–present

Adhoc Reviewer, International Journal of Gynecologic Cancer, 1998–present

Adhoc Reviewer, International Journal of Radium Oncology, 1998–present

Adhoc Reviewer, Journal of Clinical Oncology, 1999–present

Adhoc Reviewer, American Journal of Pathology, 2001–present

Adhoc Reviewer, American Journal of Obstetrics and Gynecology, 2005–present

**Other Editorial and Review Activities**

Editor, Help Break the Silence.Talk about Ovarian Cancer, National Ovarian Cancer Coalition - NOCC Editors Event; New York, NY, April 29, 2008

**TEACHING****Teaching Within Current Institution – Banner MD Anderson Cancer Center****Formal Teaching****Courses Taught**

N/A

**Training Programs**

N/A

**Other Formal Teaching**

Lecturer, 1995-1999, Gynecologic Oncology for Enterostomal Therapy Nurses / Role of Gynecologic Oncologist talk given twice a year 1995–1999

Lecturer, 1998, Advances in Research for Ovarian Cancer / Sprint for Life Symposium 1998

Lecturer, 1998, Ovarian Cancer Treatment: Molecular Approaches / Grand Rounds 1998

Lecturer, 1999, Advances and Innovations in Ovarian Cancer / Sprint for Life Symposium 1999

**Supervisory Teaching****Committees****Advisory Committees**

Thesis Advisory Committee, GSBS, Christine Lee, MD, 2001–2003

Thesis Advisory Committee, GSBS, David Crotzer, MD, 2002–2004

Thesis Advisory Committee, GSBS, Monique Nillson, 2003–2005

**Supervisory Committees**

Chair, Thesis Supervisory Committee, GSBS, David Crotzer, MD, 2002–2004

**Examining Committees**

N/A

**Direct Supervision****Undergraduate and Allied Health Students**

N/A

**Medical Students**

4+ Year Medical Students- Midwestern University, Phoenix, AZ

**Graduate Students**

GSBS, David Crotzer, MD, 2002–2004

**Postdoctoral Research Fellows**

Tae-Eu Kim Koreai, 1996–1997

Basic Science, Lois Ramondetta, MD, 1998

Basic Science, Pedro Ramirez, MD, 1998  
Basic Science, Susan Modesitt, MD, 1999  
Basic Science, Veronica Schimp, DO, 2000  
Basic Science, Janos Tanyi, 2001–2004  
Basic Science, Dwayne Jenkins, MD, 2001  
Basic Science, David Crotzer, MD, 2002–2004

**Clinical Residents and Fellows**

Diljeet Singh, 7/1996–6/1999  
Kenny Bozorgi, 7/1996–6/1999  
Terri Pustilnik, 7/1996–6/1999  
Lois M. Ramondetta, 7/1997–6/2000  
Lynn P. Parker, 7/1997–6/2000  
Mary E. Gordinier, 7/1997–6/2000  
Carlos Herrera, 7/1998–6/2001  
Lloyd West, 7/1998–6/2001  
Pedro T. Ramirez, 7/1998–6/2001  
Jubilee Brown Robinson, 7/1999–6/2002  
Matthew Anderson, 7/1999–6/2002  
Susan Modesitt, 7/1999–6/2002  
Hyun Shvartsman, 7/2000–6/2003  
Sean Tedjerati, 7/2000–6/2003  
Veronica Schimp, 7/2000–6/2003  
Alfred Dwayne Jenkins, 7/2001–6/2004  
Amir Jazaeri, 7/2001–6/2004  
Jonathan Oh, 7/2001–6/2004  
Christine Lee, 7/2001–6/2005  
Michael Frumovitz, 7/2001–6/2005  
Sachin Apte, 7/2001–6/2005  
Brian Slomovitz, 7/2002–6/2006  
David Crotzer, 7/2002–6/2006  
Premal Thaker, 7/2002–6/2006  
Salvador Saldivar, 7/2003–6/2006  
Charles Landen, 7/2003–6/2007  
Pamela Soliman, 7/2003–6/2007  
Aparna Kamat, 7/2004–6/2008  
Kathleen Schmeler, 7/2004–6/2008  
Liz Han, 7/2004–6/2008  
Michael Milam, 7/2005–6/2009  
William Merritt, 7/2005–6/2009  
Yvonne Lin, 7/2005–6/2009  
John Moroney, 7/2006–6/2010  
Robin Lacour, 7/2006–6/2010  
Shannon Westin, 7/2006–6/2010  
Whitney Spannuth, 7/2006–6/2010  
Alpa Nick, 7/2007–6/2011  
Celestine Tung, 7/2007–6/2011  
Larissa Meyer, 7/2007–6/2011  
Jennifer Kelly Burzawa, 7/2008–6/2012  
Matthew Peter Schlumbrecht, 7/2008–6/2012  
Rebecca Lynn Stone, 7/2008–6/2012

**Other Supervisory Teaching**

Julie Huh, 4th year medical student, Graduate Students, 1996  
Lisa Bazzett, Clinical Residents and Fellows, 1997

Mentor, Global Academic Programs - University Hospital Juan Canalejo, Spain, Ovidio Fernandez-Calvo, MD, Foreign Visitor, 2/2009–5/2009

Mentor, Sister Institution Associates - Fudan Cancer Hospital, China, Global Academic Programs, Jie Tang, MD, Foreign Visitor, 6/2009–12/2009

**Teaching Outside of Current Institution****Formal Teaching****Courses Taught**

Current Directions in Cancer Therapy & Research, National Ovarian Cancer Coalition

Yearly, 1998–present

A-Z Gene Therapy Replacing p53 to achieve antitumor effect, Society of Gynecologic Oncologists

Lecturer, Gene Therapy for Gynecologic Malignancies, University of Texas Medical School

**Supervisory Committees**

PhD Committee, Lee Seabrooke, Arizona State University, Tempe, AZ

**CONFERENCES AND SYMPOSIA****Organization of Conferences/Symposia (Include chairing session)**

N/A

**Presentations at National or International Conferences****Invited**

Characterization of two populations of the human ovarian cancer cell line, 2774, that express different levels of epidermal growth factor receptor, AACR Annual Meeting, 1993



Characterization of two populations of the human ovarian cancer cell line, 2774, that express different levels of epidermal growth factor receptor, Felix Rutledge Society Annual Meeting, 1993

Enhanced c-erbB-2/neu expression in human ovarian cancer cells correlates with more severe malignancy that can be suppressed by E1A, American Radium Society Annual Meeting, Aruba, 1993

Relationship between expression of c-erbB2/neu and the malignant phenotype of a human ovarian cancer cell line (SKOV3), Felix Rutledge Society Annual Meeting, 1993

Expression of adenovirus  $\beta$ -galactosidase in rhesus monkey cervix and growth inhibition of human cervical cancer cells by recombinant p53, Felix Rutledge Society Annual Meeting, 1995

Growth inhibition of human cervical cancer cells by the recombinant adenovirus-mediated transfer of a wild-type p53 gene, Society of Gynecologic Oncologists 26th Annual Meeting, San Francisco, CA, 1995

The significance of cone biopsy margins in patients with adenocarcinoma in situ of the cervix, Felix Rutledge Society Annual Meeting, 1995

A-Z Gene Therapy - Replacing p53 to achieve antitumor effect, Society of Gynecologic Oncologist, 1997

Growth inhibition of human ovarian cancer cells by combination treatment with cisplatin and transfection with adenovirus-mediated p53, Society of Gynecologic Oncologists 28th Annual Meeting, Phoenix, AZ, 1997

Replacing p53 to Achieve an Antitumor Effect, Society of Gynecologic Oncologist 28th Annual Meeting, Phoenix, AZ, 1997

Growth suppression of human ovarian cancer cell lines by the introduction of a P16 via a recombinant adenovirus, Society of Gynecologic Oncologists Annual Meeting, 1998

Cirugia Citorreductora VS Cirugia Minimay uimioterapia Adyuvante, Sociedad Venezolana De Oncologia, VIII Congreso Venezolano De Oncologia, Puerto La Cruz, Venezuela, 10/9/1998

Ganglio Centinela En El Manejo Del Cancer Vulva, Sociedad Venezolana De Oncologia, VIII Congreso Venezolano De Oncologia, Puerto La Cruz, Venezuela, 10/9/1998

Principios De Terapia Genetica Aplicados A Oncologia Media, Sociedad Venezolana De Oncologia, VIII Congreso Venezolano De Oncologia, Puerto La Cruz, Venezuela, 10/9/1998

Terapia Genetica En Cancer, Sociedad Venezolana De Oncologia, VIII Congreso Venezolano De Oncologia, Puerto La Cruz, Venezuela, 10/9/1998

Gene Therapy for Gynecologic Malignancies, Department of Gynecology Grand Rounds, University of Texas Medical School, Houston, TX, 9/28/1999

A phase I trial of ADP53 for ovarian cancer patients: Correlation with p53 and anti-adenovirus AB status, Society of Gynecologic Oncologist Annual Meeting, 2000

A Phase I Trial of Adp53 for Patients with Platinum- and Paclitaxel-Resistant Epithelial Ovarian Cancer, 31st Annual Meeting of the Society of Gynecologic Oncologists, San Diego, CA, 2/9/2000

Prognostic Factors in Endometrial Cancer, Society of Gynecologic Oncologists 2000 Winter Meeting, Park City, UT, 3/18/2000

Effect of Transfecting P16 & P53 Suppressors on Cell Growth and Apoptosis in Ovarian Cancer Cell Lines, American Association for Cancer Research, 91st Annual Meeting, San Francisco, CA, 4/1/2000

Womens Professional Development, Association of American Medical Colleges Professional Development Seminar for Junior Women Faculty, Association of American Medical Colleges, Reston, VA, 4/1/2000

A Phase I Trial of Adp53 (RPR/INGN 201) for Ovarian Cancer Patients: Correlation with P53 and Anti-Adenovirus Antibody Status, American Society of Clinical Oncology, New Orleans, LA, 5/22/2000

Gene Therapy in Patients with Epithelial Ovarian Cancer, Gynecologic Oncology Group, 7/2000

Application of Molecular Biology in Gynecologic Cancer, Annual Meeting of the Thai Gynecologic Oncology Group, Nakorn Nayok, Thailand, 8/12/2000

The Role of Liposomal Doxorubicin (Caelyx) in Ovarian Cancer, Annual Meeting of the Thai Gynecologic Oncology Group, Nakorn Nayok, Thailand, 8/12/2000

Gene Therapy for Cervical Cancer - An Update, 2nd Annual International Conference on Cervical Cancer, Houston, TX, 4/13/2002

In Vivo Adenovirus-Mediated p16 Tumor Suppressor Gene Therapy in Ovarian Cancer, Texas Forum on Female Reproduction 8th Annual Meeting, Houston, TX, 5/2/2002

A Phase II Study of Xeloda in Patients with Chemotherapy Resistant Recurrent Ovarian Cancer, ASCO 2002 Annual Meeting, Orlando, FL, 5/19/2002

The Role of Docetaxel in Gynecologic Malignancies, 40th Japanese Society of Clinical Oncology Annual Meeting, Juntendo University, Tokyo, Japan, 10/16/2002

Management of Ovarian cancer in the 21st Century-Surgery, Chemotherapy, and Molecular Therapy, 40th Japanese Society of Clinical Oncology Annual Meeting, Jutendo University, Tokyo, Japan, 10/17/2002

Surgical Management of Gynecologic Malignancies, 40th Japanese Society of Clinical Oncology Annual Meeting, Jutendo University, Tokyo, Japan, 10/17/2002

A Phase I/II Study to Evaluate the Optimum Biologic Dose of PEG-Intron in Patients with Platinum-Resistant Ovarian, Peritoneal, or Fallopian Tube Cancer, 11th SPORE Investigators Workshop, Baltimore, WA, 7/8/2003

A Phase I/II Study to Evaluate the Optimum Biologic Dose of PEG-Intron in Patients with Platinum-Resistant Ovarian, Peritoneal, or Fallopian Tube Cancer, 11th SPORE Investigator's Workshop, Baltimore, MD, 7/9/2003

P53 Targeted Therapy, 4th International Ovarian Cancer Conference, MSKCC, New York, NY, 9/11/2003

mTOR inhibition is a rational target for the treatment of endometrial cancer, ASCO 40th Annual Meeting, New Orleans, LA, 6/5/2004

Cervical and Endometrial Cancers - Preferred Treatment and Management Options, CME Conference, Hoag Cancer Center, Huntington Beach, CA, 1/28/2005

Health issues and risk factors for Breast and Gynecologic Cancers, Hadassah Check it Out program, San Antonio, TX, 2/9/2005

Cervical Cancer, Ovarian Cancer: What We Need to Know, Women's Health On Alert, Wellesley College, Wellesley, MA, 4/2/2005

Wiley, Miryam (Townsmen Correspondent) Women and hormonal health the expert views., The Wellesley Townsman: townonline.com, Wellesley College, Wellesley, MA, 4/7/2005

Transitioning from Fellow to Faculty: How to go About Setting up an Independent Laboratory, and How to be a Mentor for Students, Residents and Fellows, 2005 Southern Regional Professional Development Conference - Successful Strategies for Women in Academic Medicine, Little Rock, AR, 4/16/2005

The Role of COUP-TFII in Ovarian Cancer, Grand Rounds, Baylor College of Medicine, Houston, TX, 5/6/2005

Biologic Therapies Should be Used as Single Agents in Ovarian Cancer Clinical Trials, Felix Rutledge Society 36th Annual Meeting, Mackinac Island, MI, 7/15/2005

Surgical Treatment of Ovarian Cancer Indications and Advances in the 21st Century, Chinese Society of Gynecologic Oncology, Tsinghua University, Nanjing, China, 6/3/2006

Surgical Treatment of Ovarian Cancer Indications and Advances in the 21st Century and Beyond, International Forum on the Mechanisms and Management of Ovarian Cancer, Peking University People's Hospital, Beijing, China, 6/9/2006  
Thymidine Kinase Inhibitors in Gynecologic Malignancies, Felix Rutledge Society 36th Annual Meeting, Berlin, Germany, 9/7/2006  
Intraperitoneal Chemotherapy for Optimally Debulked Ovarian Cancer and Emerging Therapies in Ovarian Cancer, 6th Samsung Medical Center - M. D. Anderson Cancer Center International Symposium, Seoul, Korea, Republic of, 11/4/2006  
Ovarian Carcinoma for the General Oncologist, Third Symposium, Pursuit of Excellence: Addressing Issues and Trend in Oncology Nursing, UT M D Andersons Physicians Network, Santa Barbara, CA, 7/13/2007  
Early Detection and Treatment of Ovarian Cancer, SGO, Tampa, FL, 3/9/2008  
Optimizing Treatment Choices in Ovarian Cancer, SGO, Tampa, FL, 3/9/2008  
Advances in the Management of Ovarian Stromal Tumors, ASCO, Chicago, IL, 5/31/2008  
Ovarian Cancer, Uterine Cancer, Cervical Cancer, Hospital Israelita Albert Einstein and M D Anderson Cancer Center, Hospital Israelita Albert Einstein and M D Anderson Cancer Center, Sao Paulo, Brazil, 6/17/2008  
Minimally Invasive Surgery in Gynecology Oncology, II International Symposium of Gynecology Oncology - Hospital Sirio-Libanês, Sao Palo, Brazil, 11/7/2008  
Gene Therapy and Targeted Therapies in Gynecologic malignancies, II International Symposium of Gynecology Oncology - Hospital Sirio-Libanês, Sao Palo, Brazil, 11/8/2008  
Gynecologic Cancers.What you need to know about Ovarian, Uterine, and Cervix Cancers, Albert Einstein Instituto Israelita De Ensino E Pesquisa, Sao Paulo, Brazil, 6/23/2009  
Course Director, 8th International Conference on Ovarian Cancer, Memorial Sloan-Kettering Cancer Center, New York, NY, 9/24/2009  
Treatment of Ovarian Cancer 21st Century and Beyond, 6th Chinese Conference on Oncology and the 9th Cross-Strait Conference on Oncology, Fudan University Shanghai Cancer Center, Shanghai, China, 5/21/2010  
Chemotherapy Session Moderator, The 9<sup>th</sup> International Conference on Ovarian Cancer, Houston, TX 12/2/2011

### Scientific Exhibitions

Current Directions in Cancer Therapy & Research, Cancer in Women: A Comprehensive Scientific Symposium on the Gynecologic Malignancies, National Ovarian Cancer Coalition, San Diego, CA, 2/4/2000  
The Role of Gemcitabine in Ovarian Cancer, Lilly Oncology Advisory Meeting, Indianapolis, IN, 2/28/2002  
Current and New Treatment Strategies for Ovarian Cancer, Grand Rounds, University of Medicine & Dentistry of New Jersey, Newark, NJ, 3/27/2002  
Challenging Cases in Gynecologic Oncology, Network for Oncology Communication & Research, Las Vegas, NV, 8/17/2002  
Cancer in Women: A scientific update in prevention, screening, treatment and risk management for ovarian and cervical malignancies, National Ovarian Cancer Coalition, Inc., Boston, MA, 10/10/2002  
Ethical Delima's in Clinical Trials, John J. Molitar Lectureship CME Conference, University of California, Irvine, CA, 10/30/2002  
The Application of Gene Therapy for Gynecologic Malignancies, Texas Medical Center Gene Therapy Symposium, Houston, TX, 11/11/2002  
Indication for and Value of Screening for Ovarian Cancer, CME Conference, Inova Institute of Research & Education, Fairfax, VA, 11/15/2002  
Treatment of recurrent Ovarian Cancer, Grand Rounds, Walter Reed Army Medical Center, Bethesda, MD, 12/4/2002  
Current Treatment Strategies for Gynecologic Cancers, SGO Symposium 34th Annual Meeting, New Orleans, LA, 2/2/2003  
Panel Physician - Ovarian Cancer Panel, The National Comprehensive Cancer Network on Ovarian Cancer Panel, Chicago, IL, 2/7/2003  
Novel Therapeutics for Endometrial Cancer, 2003 SGO Winter Meeting, Breckenridge, CO, 3/7/2003  
Novel Approaches to the Treatment of Gynecological Cancer, 2003 Oncology Forum, Fox Chase Cancer Center, Philadelphia, PA, 4/26/2003  
Satellite Broadcast, Highlights from ASCO 2003, American Academy of the CME, Inc., Newark, NJ, 6/18/2003  
What's New in Ovarian Cancer Treatment, NOCC National Conference, Ft. Lauderdale, FL, 11/8/2003  
Ovarian Cancer: A Progress Report, 4th Annual Primary Care and Prevention conference, Atlanta, GA, 10/25/2004  
Current & New Treatments for Ovarian Cancer, NOCC Conference, Philadelphia, PA, 10/30/2004  
Clinical Trials, NOCC National Meeting, Ft. Lauderdale, FL, 11/13/2004  
Cancer In Women: a Scientific Update on Ovarian Cancer-Prevention, Screening and Treatment, CME Conference, CME Massachusetts Medical Society & NOCC, 2/4/2005  
Phase II Trials among the Ovarian SPORE Programs, Ovarian State of the Science Meeting - GOG Retreat, Bethesda, MD, 9/15/2005  
Challenging Cases in Women's Health Recurrent Ovarian Cancer at 8 Months, NMCR Challenging Cases in Gyn Oncology and Breast Cancer, Miami, FL, 6/17/2006  
How to Survive and Thrive as a Female Physician in Gynecologic Oncology, Japanese Society of Gynecologic Oncology 42nd Annual Meeting, Toyko, Japan, 6/28/2007  
What's New Gynecologic Oncology? An Update on Translational and Clinical Research, Japanese Society of Gynecologic Oncology 42nd Annual Meeting, Toyko, Japan, 7/2/2007  
Ovarian Carcinoma for the General Oncologist, UT M D Anderson Cancer Center and M D Anderson Physicians Network 3rd Annual Symposium

The University of Texas MD Anderson Cancer Center, Santa Barbara, CA, 7/9/2007 Ovarian Expert Recap - Clinical Options, ASCO, Chicago, IL, 5/30/2008 Controversial Issues in Recurrent Ovarian Cancer, Felix Rutledge Society Meeting, Buenos Aires, Argentina, 4/29/2009

Conversations with Oncology Investigators, Bridging the Gap between Research and Patient Care, Research to Practice CME Program, 01/2013

#### **National Seminar Invitations**

Attended, Association of American Medical Colleges Professional Development Seminar for Junior Women Faculty. Reston, Virginia, April 1-4, 2000

Gynecologic Cancers 2003 Treatment Update, CHRISTUS Spohn Shoreline Tumor Conference-CME, CHRISTUS Spohn Shoreline, Corpus Christi, TX, 8/27/2003

Update in the Management of Ovarian Cancer, Symposium on Women's Cancer, The Cleo Craig Memorial Cancer and Research Clinic, Lawton, OK, 8/28/2004

Palliative Care Issues for Patients Facing Advanced Ovarian Cancer, MDACC Physicians Network, Christus Schumpert Cancer CME Symposium, MDACC Physicians Network, Christus Schumpert Cancer CME Symposium, Shreveport, LA, 10/22/2004

PV, The Abnormal Pap Smear, and Cervical Cancer, MDACC Physicians Network, Christus Schumpert Cancer CME Symposium, MDACC Physicians Network, Christus Schumpert Cancer CME Symposium, Shreveport, LA, 10/22/2004

Metastatic Cervical Cancer, Cancer 2005: Preferred Treatment and Management Options, Hoag Cancer Center CME Oncology Meeting, Huntington Beach, CA, 1/28/2005

Recurrent Endometrial Cancer, Cancer 2005: Preferred Treatment and Management Options, Hoag Cancer Center CME Oncology Meeting, Huntington Beach, CA, 1/28/2005

Clinical Trials - Understanding, Navigating & Accessing Clinical Trials, Georgia Ovarian Cancer Awareness Conference, Georgia Ovarian Cancer Awareness Conference, Atlanta, GA, 2/19/2005

Cervical Cancer, Ovarian Cancer: What We Need to Know, Women's Health on Alert, Wellesley College, Wellesley, MA, 4/2/2005

Recurrent Endometrial Cancer Case#5, Challenging Cases in Women's Health, NOCR, Las Vegas, NV, 8/6/2005

Breaking Sound Barriers: Cutting Edge Research from the Lab and Clinical Trials, Turn the Volume Up-Ovarian Cancer National Alliance Conference, NOCC, Atlanta, GA, 9/29/2005

Clinical Trials 101, Turn the Volume Up-Ovarian Cancer National Alliance Conference, NOCC, Atlanta, GA, 9/29/2005

Risk Factors and Genetic Risk factors Regarding Ovarian Cancer, Diagnosis and Treatment of Ovarian Cancer - Beyond Chemotherapy National Ovarian Cancer Coalition Symposium, NOCC, Philadelphia, PA, 10/29/2005

Clinical Trials, National Ovarian Cancer Coalition Mini-Conferences, NOCC, Silver Springs, MD, 11/12/2005

Current & New Treatments for Ovarian Cancer, Grand Rounds, Advocate Christ Medical Center, Oak Lawn, IL, 1/12/2006

Progress and Treatment for Ovarian Cancer, Grand Rounds CME, MacNeal Hospital, Berwyn, IL, 4/25/2006

Women and Cancer: A Focus on Cervical and Ovarian Cancer, Oncology Nursing and Pharmacy Conference Series 2006: Collaboration for Advancing the Quality of Community Cancer Care, UTMB Office of Continuing Education, San Diego, CA, 11/18/2006

Women and Cancer: A Focus on Cervical and Ovarian Cancer, Oncology Nursing and Pharmacy Conference Series 2006: Collaboration for Advancing the Quality of Community Cancer Care, UTMB Office of Continuing Education, Williamsburg, VA, 12/2/2006

Future Directions and New Frontiers in Individualized Therapeutic Approaches, SGO-CME Certified Satellite Symposium Management of Recurrent Epithelial Ovarian Cancer: Current Standards and Novel Approaches, Society of Gynecologic Oncologist, San Diego, CA, 3/5/2007

Treatment of a Patient with Recurrent, Platinum-Resistant Disease, SGO-CME Certified Satellite Symposium Management of Recurrent Epithelial Ovarian Cancer: Current Standards and Novel Approaches, Society of Gynecologic Oncologist, San Diego, CA, 3/5/2007

Northwestern Prentice Women's Hospital, Guest Speaker, Chicago, IL. 02/08/2008 "From Bench to Bedside - My Personal Experience

Texas Medical Association, Ovarian Cancer Advisory Panel Meeting, Austin, TX, July 21, 2008

EIF Callaway Golf Foundation Women's Cancer Initiative Annual Meeting, "Ovarian Cancer Research Program", Carlsbad, CA, August 8, 2008

The Impact of Stress, Gynecologic Cancer Foundation, NYU Langone Medical Center, New York, NY, 11/1/2008

Global Academic Programs (formerly Sister Institution Conference MDACC), Chair the Working Group on Gynecologic Malignancies, Houston, TX, 6/6/2008

M D Anderson Cancer Center Development Symposium, accompanied Dr. Mendelsohn and spoke at the Southern Hills Country Club, Tulsa, OK, June 24, 2008

Gastrointestinal Cancer Retreat and PI3K Workshop: CCSG Programs Onstead Auditorium, BSRB Mitchell Building

Advisor, Entereg Complex Gynecologic Surgery Advisory Meeting, GSK, Philadelphia, PA, December 5-6, 2008

Texas Medical Association, Ovarian Cancer Advisory Panel Meeting, Austin, TX, January 9, 2009

Advisor, Yondelis Advisory Board Meeting, Centocor Ortho Biotech, Newport Beach, CA, February 20-21, 2009

Texas Medical Association, Ovarian Cancer Advisory Panel Meeting, Austin, TX, July 14, 2009

Career Pathways for Women in Science and Medicine & What the Careers of the Future Will Hold and More, Dinner with the Experts, Spring Branch Independent School District, Houston, TX, January 21, 2010

Faculty, CE-Continuing Education Program, OncoBeat ASCO 2010: Reporting the News. Beating Cancer. Educational Concepts Group, LLC; Chicago, IL; June 7, 2010.

Advanced Ovarian Cancer, Facilitator for Interactive Case Discussions, SGO, March 26, 2012

Guest Speaker, "The Ethics of Clinical Trials", Phoenix Chapter of Association of Clinical Research Professionals, July 2013

#### **Lectureships/Visiting Professorships**

Gynecologic Oncology Overview, Grand Rounds, Beaumont Hospital, Beaumont, TX, 4/17/1997

Abnormal Uterine Bleeding & Endometrial Cancer, Grand Rounds, St. Frances Cabrini Hospital, Alexandria, LA, 8/24/1999

Gynecologic Oncology Overview, Grand Rounds, Nacogdoches/San Augustine Medical Society, Nacogdoches, TX, 11/10/1999

Gene Therapy for Gynecologic Malignancies, University of Minnesota Fellowship Program, Minneapolis, MN, 12/14/1999

Gynecologic Cancers: Diagnosis, Treatment & Outcomes-Where We've Been & Where We're Going, Grand Rounds, Christus Spohn Health System Tumor Conference, Corpus Christi, TX, 9/20/2000

Current and New Treatment Strategies for Ovarian Cancer, CME, University of Medicine & Dentistry of New Jersey, Medical School, Newark, NJ, 3/27/2002

Ethical Dilemmas in Clinical Trials, John J. Molitor Lectureship, University of California, Irvine, CA, 10/30/2002

The Application of Gene Therapy for Gynecologic Malignancies, Texas Medical Center Gene Therapy Symposium, Texas Medical Center, Houston, TX, 11/11/2002

Indication for and Value of Screening for Ovarian Cancer, CME, Inova Institute of Research & Education, Fairfax, VA, 11/15/2002

Treatment of recurrent Ovarian Cancer, CME, Walter Reed Army Medical Center, Bethesda, MD, 12/4/2002

Novel Therapeutics for Endometrial Cancer, 2003 SGO Winter Meeting, Society of Gynecologic Oncologists, Breckenridge, CO, 3/7/2003

Physician Advisor for Gynecological Cancer Advisory Board, Novel Approaches to the Treatment of Gynecological Cancer, 2003 Oncology Forum, Fox Chase Cancer Center, Philadelphia, PA, 4/26/2003

Translational Research from Bench to Bedside One Gynecologic Oncologist's Experience, Bench to Bedside Symposium, NYU Medical Center, New York, NY, 5/20/2005

Progress and Treatment of Ovarian Cancer, MDACC Faculty Speakers Bureau, CME - OB/GYN Grand Rounds, St. David's Healthcare, Austin, TX, 10/18/2005

Progress and Treatment of Ovarian Cancer, MDACC Faculty Speakers Bureau, CME - University Hospital Grand Rounds, University Health Care System, Augusta, GA, 10/20/2005

Current and New Treatments for Ovarian Cancer, CME, Advocate Christ Hospital, Oak Lawn, IL, 1/12/2006

The Ethics of Clinical Trials, University of Minnesota Gynecologic Oncology Consensus Conference, University of Minnesota, Minneapolis, MN, 5/8/2006

Comprehensive Management of Ovarian Cancer: Current Treatment and Maximizing Quality of Life, CME-Medical Communications Media, Novato Community Hospital, Novato, CA, 5/7/2007

Comprehensive Management of Ovarian Cancer: Current Treatment and Maximizing Quality of Life, Grand Rounds-Medical Communications Media, University of Pittsburgh, Pittsburgh, PA, 6/5/2007

Treatment of Ovarian Cancer - 21st Century and Beyond, Grand Rounds, UC Davis Medical Center, Gynecologic Oncology, Sacramento, CA, 12/17/2008

Gynecologic Cancers: Uterine Cancer, CME: Update on Endometrial Cancer, Citizens Medical Center, Office of Continuing Medical Education, Victoria, TX, 1/11/2010

#### **NATIONAL CONFERENCES- INVITED/ AND OR SPEAKER**

Treatment of Ovarian Cancer, National Ovarian Cancer Coalition State Chapters Meeting, NOCC, Ft. Lauderdale, FL, 11/5/1999

Commencement speaker, East Liverpool High School, East Liverpool, OH, 6/1/2000

Gynecologic Cancers: Diagnosis, Treatment & Outcomes-Where We've Been & Where We're Going, 2nd Annual "Closing Gaps & Opening Doors Conference for Working Women, U.S. Department of Labor, Women's Bureau Region VI, Austin, TX, 10/5/2000

Talk-back Session - Moderator, Wet State Theater, Alley Theater, UT M D Anderson Cancer Center & the Stanford Foundation, Austin, TX, 5/31/2001

Interferon-gamma in the Management of Ovarian Cancer clinical Advisory Program, Advisory Program, InterMune Pharmaceuticals, Houston, TX, 6/21/2001

Current & New Treatments for Ovarian Cancer, Cancer in Women: A Scientific Update in Prevention, Screening and Treatment for Ovarian Cancer, NOCC, Houston, TX, 1/1/2004

Management of Gynecologic Cancer, Sanofi-Synthelabo Oncology Health Science Advisory Board Meeting, Sanofi-Synthelabo Oncology, Dallas, TX, 4/24/2004

Controversies in Ovarian Cancer, ACOG Update, Audiotaped Tele-Conference, ACOG, Houston, TX, 5/14/2004

Health issues and risk factors for Breast and Gynecologic Cancers, Hadassah Check it Out program to educate young women in Houston Independent School District, Worthing High School, Houston, TX, 2/9/2005

Screening for Gynecologic Cancers, CME Memorial Hermann Southwest Hospital, Memorial Hermann Southwest Hospital, Houston, TX, 3/8/2005

The Role of COUP-TFII in Ovarian Cancer, Arthur M. Faris, Sr., MD Resident Research Day, Baylor College of Medicine, Obstetrics and Gynecology, Houston, TX, 5/6/2005

Menopause The Musical Out Loud - Breaking the Silence on Ovarian Cancer, National Ovarian Cancer Coalition, Matrix Graphix, and Ovarian Cancer National Alliance Aging Out Loud Tour, TOC Productions Inc., www.menopausethemusical.com, National Ovarian Cancer Coalition, Stafford, TX, 3/3/2006

Progress and Treatment of Ovarian Cancer, National Ovarian Cancer Coalition, American Cancer Society, National Ovarian Cancer Coalition, American Cancer Society, Austin, TX, 3/20/2006

What you need to know - Hereditary Breast and Ovarian Cancer, UT M D Anderson Cancer Center and The San Antonio Chapter of Hadassah, San Antonio, TX, 10/26/2006

Progress and Treatment for Ovarian Cancer, UTMB - CME Grand Rounds, Galveston, TX, 2/14/2007

Moderator - Stump the Professor, 37th Annual Meeting of the Felix Rutledge Society, Houston, TX, 6/13/2007

Ovarian Cancer Advisory Panel, Physician Oncology Education Program, Ovarian Cancer Advisory Panel Meeting, Texas Medical Association, Austin, TX, 12/10/2007

Cervical Cancer Update Including the Role of Vaccines, SGO-Society of Gynecologic Oncologist, Educational Concepts Group, LLC, Oncobeat SGO: Reporting the News.Beating Cancer, San Antonio, TX, 2/8/2009

Wolf, JK. Strategies for the Management of Platinum-Resistant Ovarian Cancer, 41st Annual Meeting on Women's Cancer Society of Gynecologic Oncologist, CBCE - University of North Texas Health Science Center at Fort Worth, Center for Biomedical Continuing Education, San Francisco, CA, 3/15/2010

Ovarian Cancer, Women's Cancer Awareness Conference, Methodist Healthcare System, San Antonio, TX, 9/30/2010

Gynecologic Oncology Overview, Grand Rounds, Beaumont Hospital, Beaumont, TX, 4/17/1997 Abnormal Uterine Bleeding & Endometrial Cancer, Grand Rounds, St. Frances Cabrini Hospital, Alexandria, LA, 8/24/1999

Gynecologic Oncology Overview, Grand Rounds, Nacogdoches/San Augustine Medical Society, Nacogdoches, TX, 11/10/1999

Gene Therapy for Gynecologic Malignancies, University of Minnesota Fellowship Program, Minneapolis, MN, 12/14/1999

Gynecologic Cancers: Diagnosis, Treatment & Outcomes-Where We've Been & Where We're Going, 2nd Annual "Closing Gaps & Opening Doors Conference for Working Women, U.S. Department of Labor, Women's Bureau Region VI, Austin, TX, 10/5/2000

Gynecologic Cancers: Diagnosis, Treatment & Outcomes-Where We've Been & Where We're Going, Grand Rounds, Christus Spohn Health System Tumor Conference, Corpus Christi, TX, 9/20/2000

Talk-back Session - Moderator, Wet State Theater, Alley Theater, UT M D Anderson Cancer Center & the Stanford Foundation, Austin, TX, 5/31/2001

Interferon-g in the Management of Ovarian Cancer clinical Advisory Program, Advisory Program, InterMune Pharmaceuticals, Houston, TX, 6/21/2001

Current and New Treatment Strategies for Ovarian Cancer, CME, University of Medicine & Dentistry of New Jersey, Medical School, Newark, NJ, 3/27/2002

Ethical Delima's in Clinical Trials, John J. Molitar Lectureship, University of California, Irvine, CA, 10/30/2002

The Application of Gene Therapy for Gynecologic Malignancies, Texas Medical Center Gene Therapy Symposium, Texas Medical Center, Houston, TX, 11/11/2002

Indication for and Value of Screening for Ovarian Cancer, CME, Inova Institute of Research & Education, Fairfax, VA, 11/15/2002

Treatment of recurrent Ovarian Cancer, CME, Walter Reed Army Medical Center, Bethesda, MD, 12/4/2002

Novel Therapeutics for Endometrial Cancer, 2003 SGO Winter Meeting, Society of Gynecologic Oncologist, Breckenridge, CO, 3/7/2003

Physician Advisor for Gynecological Cancer Advisory Board, Novel Approaches to the Treatment of Gynecological Cancer, 2003 Oncology Forum, Fox Chase Cancer Center, Philadelphia, PA, 4/26/2003

Current & New Treatments for Ovarian Cancer, Cancer in Women: A Scientific Update in Prevention, Screening and Treatment for Ovarian Cancer, NOCC, Houston, TX, 1/1/2004

Management of Gynecologic Cancer, Sanofi-Synthelabo Oncology Health Science Advisory Board Meeting, Sanofi-Synthelabo Oncology, Dallas, TX, 4/24/2004

Controversies in Ovarian Cancer, ACOG Update, Audiotaped Tele-Conference, ACOG, Houston, TX, 5/14/2004

Health issues and risk factors for Breast and Gynecologic Cancers, Hadassah Check it Out program to educate young women in Houston Independent School District, Worthing High School, Houston, TX, 2/9/2005

Screening for Gynecologic Cancers, CME Memorial Hermann Southwest Hospital, Memorial Hermann Southwest Hospital, Houston, TX, 3/8/2005

The Role of COUP-TFII in Ovarian Cancer, Arthur M. Faris, Sr., MD Resident Research Day, Baylor College of Medicine, Obstetrics and Gynecology, Houston, TX, 5/6/2005

Translational Research from Bench to Bedside One Gynecologic Oncologist's Experience, Bench to Beside Symposium, NYU Medical Center, New York, NY, 5/20/2005

Progress and Treatment of Ovarian Cancer, MDACC Faculty Speakers Bureau, CME - OB/GYN Grand Rounds, St. David's Healthcare, Austin, TX, 10/18/2005

Progress and Treatment of Ovarian Cancer, MDACC Faculty Speakers Bureau, CME - University Hospital Grand Rounds, University Health Care System, Augusta, GA, 10/20/2005



Current and New Treatments for Ovarian Cancer, CME, Advocate Christ Hospital, Oak Lawn, IL, 1/12/2006

Menopause The Musical Out Loud - Breaking the Silence on Ovarian Cancer, National Ovarian Cancer Coalition, Matrix Graphix, and Ovarian Cancer National Alliance Aging Out Loud Tour, TOC Productions Inc., www.menopausethemusical.com, National Ovarian Cancer Coalition, Stafford, TX, 3/3/2006

Progress and Treatment of Ovarian Cancer, National Ovarian Cancer Coalition, American Cancer Society, National Ovarian Cancer Coalition, American Cancer Society, Austin, TX, 3/20/2006

The Ethics of Clinical Trials, University of Minnesota Gynecologic Oncology Consensus Conference, University of Minnesota, Minneapolis, MN, 5/8/2006

What you need to know - Hereditary Breast and Ovarian Cancer, UT M D Anderson Cancer Center and The San Antonio Chapter of Hadassah, San Antonio, TX, 10/26/2006

Progress and Treatment for Ovarian Cancer, UTMB - CME Grand Rounds, Galveston, TX, 2/14/2007

Comprehensive Management of Ovarian Cancer: Current Treatment and Maximizing Quality of Life, CME-Medical Communications Media, Novato Community Hospital, Novato, CA, 5/7/2007

Comprehensive Management of Ovarian Cancer: Current Treatment and Maximizing Quality of Life, Grand Rounds-Medical Communications Media, University of Pittsburgh, Pittsburgh, PA, 6/5/2007

Moderator - Stump the Professor, 37th Annual Meeting of the Felix Rutledge Society, Houston, TX, 6/13/2007

Ovarian Cancer Advisory Panel, Physician Oncology Education Program, Ovarian Cancer Advisory Panel Meeting, Texas Medical Association, Austin, TX, 12/10/2007

Lecturer: Teal Lunch for Life, "Ovarian Cancer: Top Ten Questions What you really need to know..." benefiting Blanton-Davis Ovarian Cancer Research Program, San Antonio, TX, September 10, 2008

Lecturer: E2 Communications-Opinions in Gyn Malignancies: An Interactive Forum and KOL Focus Group, Las Vegas, NV, October 18, 2008

Treatment of Ovarian Cancer - 21st Century and Beyond, Grand Rounds, UC Davis Medical Center, Gynecologic Oncology, Sacramento, CA, 12/17/2008

Lecturer: Shell Health - Shell Oil Company, Prevention and Gynecological Oncology, Houston, TX, April 6, 2009

Lecturer: Raising Ovarian Cancer Awareness to Increase Survival Rates; NOCC, Media Blitz in New York, NY, April 22-23, 2009

Speaker, Teal Lunch for Life, "Ovarian Cancer: What you need to know and how you can help..." benefiting Blanton-Davis Ovarian Cancer Research Program, San Antonio, TX, Sept. 9, 2009

Speaker, Key to the Cure Benefit, "Ovarian Cancer, Raise Awareness"; NOCC & Saks 5th Avenue-Austin, Austin, TX, September 17, 2009

Cervical Cancer Update Including the Role of Vaccines, SGO-Society of Gynecologic Oncologist, Educational Concepts Group, LLC, Oncobeat SGO: Reporting the News.Beating Cancer, San Antonio, TX, 2/8/2009

Gynecologic Cancers: Uterine Cancer, CME: Update on Endometrial Cancer, Citizens Medical Center, Office of Continuing Medical Education, Victoria, TX, 1/11/2010

Speaker, CME/CNE Ovarian Cancer Knowledge Video, Texas Medical Association, Ovarian Cancer Advisory Panel Meeting, Austin, TX, January 25, 2010

Wolf, JK. Strategies for the Management of Platinum-Resistant Ovarian Cancer, 41st Annual Meeting on Women's Cancer Society of Gynecologic Oncologist, CBCE - University of North Texas Health Science Center at Fort Worth, Center for Biomedical Continuing Education, San Francisco, CA, 3/15/2010

Ovarian Cancer, Women's Cancer Awareness Conference, Methodist Healthcare System, San Antonio, TX, 9/30/2010

#### **PROFESSIONAL MEMBERSHIPS/ACTIVITIES**

##### **Professional Society Activities, with Offices Held National and International**

American Association of Cancer Research

**Member**, 1996-2014

Felix Rutledge Society

**Member**, 1996-present

**Chairman**, Program Committee, 1999

**Co-Chairman**, Program Committee, 2007

**President**, 2008-2009

Society of Gynecologic Oncology

**Member**, 1996-present

**Member**, Program Committee, 1999

**Member**, Government Relations Committee, 2002-2011

**Co-Chair**, Government Relations Committee, 2005-2011

American Society of Clinical Oncology

**Member**, 1997-present

American College of Obstetrics and Gynecology

**Fellow**, 1999-present

Gynecologic Oncology Group

**Member**, Developmental Therapeutics Committee, 2001-2011

**Member**, Phase I Subcommittee, 2004-2011

NEOMED Alumni Board

Rootstown, OH

**Member** 2008-2014



Southern Regional Professional Development Conference for Women in Medicine and Research, Take charge of Your Life: Speak Up, Stand Out, and Stay Calm

**Member**, Planning Committee, 3/2007

American Gynecological & Obstetrical Society

**Fellow**, 11/2007–present

Southwest Oncology Group (SWOG), Seattle, WA

**Member**, 11/2010–2011

**Local/State**

Houston Gynecology & Obstetrics Society, Houston, TX

**Member**, 1996

**Treasurer**, 1998–2000

**Vice President**, 2001–2002

**President-Elect**, 2002–2003

**President**, 2003–2004

**Member**, 2004–2011

Ob-Gyn Alumni Association, The University of Texas Health Science Center at San Antonio, San Antonio, TX

**Member**, 1999

American Board of Obstetrics & Gynecology, Dallas, TX

**Oral Board Examiner**, 12/2008

**Oral Examiner**, 12/2009

**Examiner**, 12/2010

**MEDIA: LOCAL AND NATIONAL**

1. News Article on Women's Health On Alert Conference: Wiley, Miryam (Townsmen Correspondent) Women and hormonal health - the expert views. The Wellesley Townsman: townonline.com, April 7, 2005
2. Lecturer, Breaking the Silence on Ovarian Cancer - Diagnosis and Treatment; NOCC, State of Disease, Teleconference in Advance of Nation's Leading Cancer Meeting, Taped in New York, NY, Televised Live Across the Nation, May 22-23, 2006
3. Lecturer, Breaking the Silence on Ovarian Cancer - Diagnosis and Treatment; NOCC Media Initiative Magazine Interview, Interviewed in New York, NY, Fitness, MEDIZine's Healthy Living, Family Circle, Prevention, Cosmopolitan, Glamour, Woman's Day, O Magazine, March 11-13, 2007
4. Lecturer, Breaking the Silence on Ovarian Cancer Campaign, NOCC Media Alert Blitz on the Consensus of Ovarian Cancer; Teleconference in Advance of Nation's Leading Cancer Meeting, Taped in Houston, Texas, Televised Live Across the Nation, June 25, 2007
5. Dr. Oz Show appearance, Birth Control Pills and Risk of Ovarian Cancer, March 2012
6. I Heart Radio, "Preview of Highlights of San Antonio Breast Cancer Society Meeting", December 2013

#### **COMMUNITY**

1. Foundation Event – Development Reception for Banner MD Anderson Cancer Center, November 3, 2011
2. Foundation Event – Presentation at Vi Community, Scottsdale, Arizona 02/2012
3. Banner Health Foundation Lunch - JoAnn Orefice, Pat McKennon and Pat Carbone Tour and Lunch, March 30, 2012
4. Foundation Event – Freeport McMoRan Employee Campaign Launch, Phoenix, AZ, April 6, 2012
5. Surgery Grand Rounds, Banner Good Samaritan Hospital, Gynecologic Oncology 2012 Updates, Phoenix, AZ, March 2012
6. Foundation Event – Bill and Anne Smith Reception, Sedona, AZ April 21, 2012
7. Foundation Event – Presentation at Vi Community, Scottsdale, Arizona 09/12/2012
8. Speaker at 4th Annual Run/Walk for Ovarian Cancer, Break the Silence, NOCC 09/23/2012
9. Speaker at Association of Physician Assistants in Oncology, 2012 Annual Conference, Scottsdale, AZ 10/13/2012
10. Obesity and Cancer, Banner Gateway Medical Center Bariatric Grand Rounds, 02/2013
11. Advanced Leadership Program for Physicians, Banner Health, 2012-2013
12. Principal-Investigator, Various Donors, UT M. D. Anderson Cancer Center, 1999-Present, \$324,834
13. Selected 2013 *Top 50 Most Influential Women in Business*

#### **NATIONAL PROFESSIONAL LECTURES/TALKS**

Lecturer: **Strengthening Her Fight in the Battle Against Ovarian Cancer; Physicians Connect-Tibotec (Doxil) Pharmaceuticals & MediMedia**

Houston, TX, October 11, 2005

Woodlands, TX October 12, 2005

Moline, IL, October 25, 2005

Monrovia, CA, October 27, 2005

Grand Rapids, MI, December 15, 2005

Kansas City, MO, January 10, 2006

Houston, TX, October 17, 2006

Oklahoma City, OK, November 14, 2006

Woodlands, TX, April 23, 2007

Oklahoma City, OK, May 8, 2007

Houston, TX, June 12, 2007

Houston, TX, June 19, 2007

Houston, TX (MDACC), June 22, 2007

Houston, TX, October 17, 2007

Houston, TX, December 5, 2007

Houston, TX, June 6, 2008

Houston, TX, May 14, 2009

Lecturer: **Latest Developments in HPV-Related Diseases and Cervical Cancer; Merck i-Med Conference**

Lubbock, TX, September 26, 2006  
Dallas, TX, October 10, 2006  
Tyler, TX, October 24, 2006  
Harvey, LA, November 16, 2006  
Beaumont, TX, November 20, 2006  
Snyder, TX, November 21, 2006  
Bedford, TX, January 18, 2007  
Denver, CO, January 30, 2007  
Houston, TX, February 13, 2007  
Baytown, TX, February 20, 2007  
Houston, TX, March 14, 2007  
Austin, TX, March 28, 2007  
Arlington, TX, May 14, 2007  
Houston, TX (MDACC), May 18, 2007  
Webster, TX, May 23, 2007  
Woodlands, TX, June 7, 2007  
Dallas, TX, June 8, 2007  
Chicago, IL, July 23, 2007  
Nacogdoches, TX, October 30, 2007  
Houston, TX, November 11, 2007  
San Antonio, TX, November 14, 2007  
Dallas, TX, December 4, 2007  
Dallas, TX, December 14, 2007  
Grapevine, TX, February 4, 2008  
SanAntonio, TX, February 18, 2008  
San Angelo, TX, February 19, 2008  
Nacogdoches, TX, February 28, 2008  
Hutchinson, KS, May 12, 2008

Lecturer: **The Management of Cervical Cancer: Focus on Hycamtin; Advanced Communication and Education (ACE) - Glaxo Smith Klein (GSK)**

Beaumont, TX, October 30, 2006  
Corpus Christi, TX, November 27, 2006  
Lafayette, LA, November 28, 2006  
Lake Charles, LA, April 2, 2007

Grand Rounds Speaker: **Comprehensive Management of Ovarian Cancer: Current Treatment and Maximizing Quality of Life; Medical Communications Media Bureau**

Casper, WY, September 11, 2007  
Pensacola, FL, October 9, 2007  
Sugarland, TX, November 9, 2007  
Houston, TX, December 4, 2007  
Victoria, TX, December 5, 2007  
Birmingham, AL, April 1, 2008  
Kansas City, MO, May 7, 2008  
St. Petersburg, FL, August 21, 2008  
Victoria, TX, December 3, 2008  
Newport Beach, CA, December 4, 2008

Lecturer: **The Treatment of Platinum-Sensitive Advanced Ovarian Cancer; Lilly Lecturer Bureau**

Houston, TX, April 3, 2007  
Harlingen, TX, 12pm & 7pm, Jan 31, 2008  
McAllen, TX, March 26, 2008  
Brownsville, TX, March 26, 2008  
Jacksonville, FL, April 23, 2008  
Houston, TX, May 5-6, 2008  
Fort Worth, TX, May 14, 2008  
Wichita Falls, TX, May 14, 2008  
Houston, TX, May 15, 2008  
San Antonio, TX, May 28, 2008  
Houston, TX, June 4, 2008  
San Antonio, TX, July 2, 2008  
Beaumont, TX, July 23, 2008  
Fort Worth, TX, August 27, 2008  
Wichita Falls, TX, August 27, 2008  
Indianapolis, IN, (3-talks), September 3, 2008  
Corpus Christi, TX, September 17, 2008  
Laredo, TX, September 17, 2008  
San Antonio, TX, October 22, 2008  
Temple, TX, May 22, 2009  
Laredo, TX, May 27, 2009  
McAllen, TX, May 28, 2009  
Houston, TX, June 4, 2009  
Houston, TX, June 17, 2009  
Beaumont, TX, August 6, 2009

**Volunteer and Advocacy**

1. Founder, Sprint for Life Fun Run, Raised over \$5 Million to Date For Ovarian Cancer Research, 1998-Present
2. National Ovarian Cancer Coalition- Member of medical advisory board 1996- 2008. Member of Governing Board 2009-present.
3. Society for Women's Health Research- Board Member 2014-present
4. Health Volunteers Overseas- 20-14- present. Volunteered in Viet Nam, Honduras, Haiti: Project Director Bhaktapur Nepal. Oncology Steering Committee Member.

CV updated; 01/05/2019

Judith K Wolf, MD

# Exhibit B

Judith Wolf, M.D.  
Materials Considered

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**Company Documents**

1. IMERYYS 088907
2. IMERYYS 210136
3. IMERYYS048311
4. IMERYYS051370
5. IMERYYS053387
6. IMERYYS088907
7. IMERYYS090653
8. IMERYYS094601
9. IMERYYS098115
10. IMERYYS105215
11. IMERYYS137677/P-594
12. IMERYYS210136
13. IMERYYS210729
14. IMERYYS219720
15. IMERYYS230366
16. IMERYYS241866
17. IMERYYS245144/P-659
18. IMERYYS248877
19. IMERYYS255101
20. IMERYYS255224
21. IMERYYS255384
22. IMERYYS255394
23. IMERYYS255395
24. IMERYYS279884
25. IMERYYS279968
26. IMERYYS281335
27. IMERYYS281776
28. IMERYYS284935
29. IMERYYS304036
30. IMERYYS304036
31. IMERYYS324700
32. IMERYYS342524
33. IMERYYS406170
34. IMERYYS422289
35. IMERYYS467511
36. IMERYYS-A\_0011817
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39. J&J S2s and BP Product Analysis (1972)
40. JANSSEN-000001/P-22

41. JANSSEN-000056/P-23  
42. JNJ 000251888  
43. JNJ000000704/P-396  
44. JNJ000011150  
45. JNJ000016645  
46. JNJ000019415  
47. JNJ000026987  
48. JNJ000030027  
49. JNJ000062359  
50. JNJ000062436  
51. JNJ000063951  
52. JNJ000064544  
53. JNJ000064762  
54. JNJ000065264  
55. JNJ000065601  
56. JNJ000087166  
57. JNJ000087710  
58. JNJ000087716  
59. JNJ000089413  
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84. JNJ000381995  
85. JNJ000404860  
86. JNJ000460665  
87. JNJ000521616



88. JNJ000526750
89. JNJ000025132
90. JNJ000046293
91. JNJ000260700
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94. JNJAZ55\_000004563
95. JNJAZ55\_000006341
96. JNJAZ55\_000008177
97. JNJL61\_000014431
98. JNJMX68\_000003728
99. JNJMX68\_000012858
100. JNJMX68\_000013019
101. JNJMX68\_000013945
102. JNJMX68\_000017827
103. JNJNL61\_000079334
104. LUZ013094/P-26
105. P-321
106. P-47
107. PCPC\_MDL00062175
108. PCPC0075758
109. RJLEE-001497
110. WCD 002478 - Exhibit 32 Waldstreicher
111. Pltf\_MISC\_00000272 (JANSSEN-000001-19) 1962.
112. RA00461
113. RA00462
114. RA00469-70
115. RA00471-72
116. RA00473
117. RA00474
118. RA00475
119. RA00476
120. RA00477-78
121. JNJTALC001465273

**Case-Specific Depositions**

Deposition of Anna Gallardo, dated 01/12/2021  
Deposition of Ramon Gallardo, dated 05/13/2021  
Deposition of David Mutch, M.D., dated 02/13/2021  
Deposition of Judith Wolf, M.D., dated 09/13/2021  
Deposition of Judith Wolf, M.D., dated 09/14/2021

**Plaintiff Profile Form**

Plaintiff Profile Form for Anna Gallardo

**Medical Records (Defense)**

GallardoA-WUSTLMR-00002-00279  
GallardoA-WUSTLMR-00001  
GallardoA-WUSMDOGMR-00014-00074  
GallardoA-WUSMDOGMR-00008-00013  
GallardoA-WUSMDOGMR-00001-00007  
GallardoA-WUCAMDMR-00002-00184  
GallardoA-WUCAMDMR-00001  
GallardoA-WoodleyM-00008-00015  
GallardoA-WoodleyM-00001-00007  
GallardoA-WCO-00001-00075  
GallardoA-TCCMR-00001-00037  
GallardoA-TAUCPCMR-00005-00048  
GallardoA-TAUCPCMR-00001-00004  
GallardoA-SJMMCRad-00001-00005  
GallardoA-SJMMCMR-00001-00110  
GallardoA-MMTSLMR-00001-00194  
GallardoA-GeneDxMR-00001-00141  
GallardoA-BJHRad-00001-00003  
GallardoA-BJHPath-00001  
GallardoA-BJHMR-00001-00031  
GallardoA-BJHCFAMMR-00003-00951  
GallardoA-BJHCFAMMR-00001-00002  
GallardoA-BabbS-00019-00020  
GallardoA-BabbS-00007-00018  
GallardoA-BabbS-00001-00006  
GALLARDO\_ANNA\_WALGREENSPHARMACY\_00001-00064  
GALLARDO\_ANNA\_DRWASSERMAN\_00001-00320  
GALLARDO\_ANNA\_DRTHOMASBARTHOLET\_00001-00076  
GALLARDO\_ANNA\_DRMUTCH\_00001-00117  
GALLARDO\_ANNA\_BJH\_00001-00049

**Medical Billing (Defense)**

GallardoAnna-WUSLPPB-00001-00031  
GallardoA-WUCAMMGPB-00004-00042  
GallardoA-WUCAMMGPB-00001-00003  
GallardoA-TAUCPCPB-00001-00006  
GallardoA-SLSCPB-00001-00006  
GallardoA-SJMMCPB-00003-00007  
GallardoA-SJMMCPB-00001-00002  
GallardoA-MMTSLPB-00002-00006  
GallardoA-MMTSLPB-00001

**Medical Records Defense (NRS)**

GallardoA-VerticchioJ-00005-00010  
GallardoA-VerticchioJ-00001-00004  
GallardoA-SLSCMR-00001-00002  
GallardoA-RichardsD-00001-00004  
GallardoA-ReddyS-00001-00005  
GallardoA-MOCPB-00001-00005  
GallardoA-MOCMR-00001-00002  
GallardoA-MLSSLPB-00009  
GallardoA-MLSSLPB-00005-00008  
GallardoA-MLSSLPB-00001-00004  
GallardoA-MCOSSPB-00006-00009  
GallardoA-MCOSSPB-00001-00005  
GallardoA-KelnovV-00001-00002  
GallardoA-JWHP-00001-00002  
GallardoA-BharadwajM-00001-00004

**Medical Records (Plaintiff)**

GALLARDO\_A\_WASHU\_00001-00211  
GALLARDO\_A\_STJOHNSMERCY\_00001-00239  
GALLARDO\_A\_MARYLANDMEDICAL\_00001-00145  
GALLARDO\_A\_GENEDX\_00001-00132  
GALLARDO\_A\_BARNES\_JEWISH\_HOSP\_00001-00329  
GALLARDO\_ANNA\_WASHU\_MED\_00212-00253  
GALLARDO\_ANNA\_WASHU\_MED\_00254-00502

**Medical Billing (Plaintiff)**

GALLARDO\_ANNA\_STJOHNMERCY\_BILLING\_0001-0018  
GALLARDO\_ANNA\_WASHU\_BILLING\_0001-0003

**Medical Records Plaintiff (NRS)**

GALLARDO\_A\_STJOHNSMERCY\_00240

**Miscellaneous**

Expert Report of John Godleski, M.D., dated 7/21/2021

Amended Expert Report of Shawn Levy, PhD

Expert Report of Bernard Harlow, PhD and Kenneth Rothman, Dr.P.H.

Expert Report of Michele Cote, PhD, MPH

MDL Johnsons' BP Application and Exposure Container Calculations for Six OVCA Victims Bellwether Cases

Second Amended Expert Report of Anne McTiernan, MD, PhD

Second Amended Expert Report of Jack Siemiatycki, PhD

Second Amended Expert Report of Rebecca Smith-Bindman, MD

Supplemental Report of Patricia Moorman, MSPH, PhD

Supplemental Report of Sonal Singh, MD, MPH

Third Supplemental MDL Report of William Longo, PhD

# Exhibit C

**Judith Wolf, MD****Medical Legal Testimony in last 4 years**

Date: January , 2019

Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability Litigation DL No. 2738

Date: August 30, 2021, and August 31, 2021

Elen Kleene v. Johnson & Johnson et al.

Court of Common Pleas, First Judicial District of Pennsylvania

Date: September 13, 2021 and September 14, 2021

Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability Litigation MDL No. 273

Date: January 10, 2022, and April 25, 2024

Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability Litigation MDL No. 273

Date: April 25, 2024

Grand Canyon Joe Carl v. Johnson & Johnson, et al.

United States District Court for the District of New Jersey

**Hourly Rate: \$650/hour**



# **EXHIBIT 37**

**PLAINTIFF PROFILE FORM**

This Plaintiff Profile Form (“PPF”) must be completed by the plaintiff or the representative of plaintiff’s decedent. In completing this PPF, you are under oath and must provide information that is true and complete to the best of your knowledge, information and belief after reasonable inquiry. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect.

In filling out this PPF, please use the following definitions: (1) “**health care provider**” means any hospital, clinic, medical center, physician’s office, infirmary, medical or diagnostic laboratory, or other facility that provides medical, dietary, psychiatric, or psychological care or advice, and any pharmacy, weight loss center, x-ray department, laboratory, physical therapist or physical therapy department, rehabilitation specialist, physician, psychiatrist, osteopath, homeopath, chiropractor, psychologist, nutritionist, dietician, or other persons or entities involved in the evaluation, diagnosis, care, and/or treatment of the plaintiff or plaintiff’s decedent; (2) “**document**” means any writing or record of every type that is in your possession, including but not limited to written documents, documents in electronic format, cassettes, videotapes, photographs, charts, computer discs or tapes, and x-rays, drawings, graphs, phone-records, non-identical copies, and other data compilations from which information can be obtained and translated, if necessary, by the respondent through electronic devices into reasonably usable form.

Information provided in this PPF will only be used for purposes related to this litigation and may be disclosed only as permitted by the protective order in this litigation. This PPF is completed pursuant to the Federal Rules of Civil Procedure governing discovery.

**1. CASE INFORMATION**

Name of Person Completing Form:	Carter	Judkins
	First	M.I. Last
If you are completing this PPF in a representative capacity (e.g., on behalf of the estate of a deceased person), please complete the following:		
Your Name:	N/A	
	First	M.I. Last
Your relationship to individual you represent:	N/A	

**THE REST OF THIS PLAINTIFF PROFILE FORM REQUESTS INFORMATION ABOUT THE PERSON WHO USED JOHNSON'S BABY POWDER AND/OR SHOWER TO SHOWER AND WAS DIAGNOSED WITH OVARIAN CANCER**

**2. PERSONAL INFORMATION**

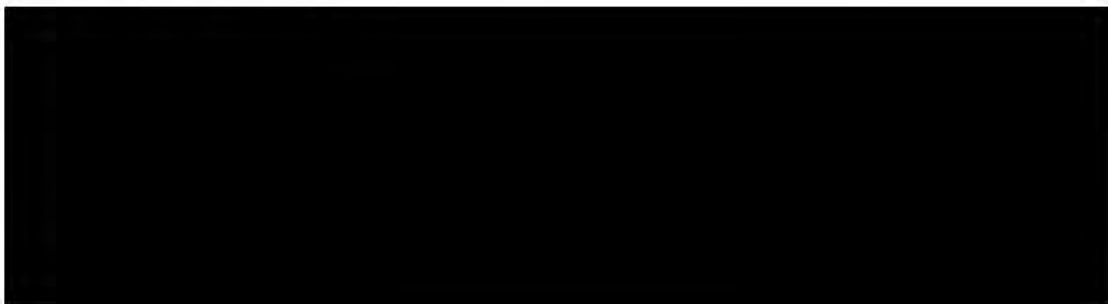
Name:	JUDKINS	CARTER
	First	M.I. Last
Maiden/Other Names Used:	Anne Judkins; Carter Judkins-Frehner	
Current or Last Known Address:	[REDACTED] Dover NH 03820	
Date of Birth:	[REDACTED] 1956	Gender: Male: <input type="checkbox"/> Female: <input checked="" type="checkbox"/>
Date of Death (If Applicable):	<input checked="" type="checkbox"/> N/A	Social Security Number: [REDACTED]
Select Marriage Status:	Name of Spouse, if Married at time of filing Complaint:	
Divorced	N/A	

3. **TALCUM POWDER-RELATED CLAIM**

- a. Have you been diagnosed with one of the following types of cancer? b. If yes, please provide the approximate date of initial diagnosis (if more than one, for each initial diagnosis). c. If you were diagnosed with ovarian cancer, fallopian tube or primary peritoneal cancer, please provide the type. d. If you were diagnosed with ovarian cancer, fallopian tube or primary peritoneal cancer, please provide the stage.

a. Type of Cancer	b. Date of Initial Diagnosis	c. Type of Ovarian, Fallopian tube, or Primary Peritoneal Cancer	d. Stage of Ovarian, Fallopian tube or Primary Peritoneal Cancer
Ovarian	Dec 30 2016	High-Grade Serous	Stage II

4. **MEDICAL HISTORY:**



c. Have you ever been diagnosed with any of the following?

Condition	Yes/No/Unknown	Name and Address of Diagnosing Provider	Approximate Date of Diagnosis (if applicable)
BRCA1 or BRCA2 mutation			
Endometriosis			
Adenomyosis			
Irregular vaginal bleeding			
Ovarian Cysts			
Polycystic ovaries and/or Polycystic Ovarian Syndrome (PCOS)			
Uterine fibroids			
Infertility			
Breast cancer			
Lynch Syndrome			

Condition	Yes/No/Unknown	Name and Address of Diagnosing Provider	Approximate Date of Diagnosis (if applicable)
Other cancer (please specify below):			
N/A			
Obesity/overweight			
Pelvic Inflammatory Disease (PID)			
Colon Polyps			



6. Other than those injuries that you believe were caused by your use of body powder, do you currently suffer from any chronic illnesses or disabilities?

**FAMILY MEDICAL HISTORY**

7. Limiting this question to blood relatives, to the best of your knowledge, please indicate whether your *parents, siblings, children, grandparents, aunts, uncles, or first cousins* have ever suffered from or been treated for any type of cancer (including but not limited to ovarian cancer or breast cancer):

Relative's Name	Relation to you	Type of cancer	Date of cancer

- \_\_\_\_\_

## HEALTH CARE PROVIDERS AND PHARMACIES

9. Limiting your answer to primary care, gynecology and oncology healthcare providers, identify each doctor or other health care provider who you have seen for medical care and treatment from the ten (10) years prior to your ovarian cancer diagnosis to the present. In particular, please use your best efforts to list all of the primary care providers during this period.

[illegible]

Doctor or Healthcare Provider's Name	Doctor or Healthcare Provider's Specialty	Address	Approximate Years of Visits
			to
			to
			to
			to
			to
			to
			to
			to
			to
			to
			to
			to
			to
			to

10. If any of your healthcare providers who you have seen in relation to treatment and care of **ovarian cancer or any other form of cancer** were not identified previously, please identify for each such provider:

Name and Specialty	Address	Approximate Years of Treatment	Reason for Treatment
		to	
		to	
		to	
		to	
		to	
		to	
		to	
		to	
		to	
		to	
		to	
		to	
		to	
		to	
		to	

11. Limiting your response to visits for issues related to cancer and to gynecologic issues other than pregnancy, identify each hospital, clinic, or health care facility where you were hospitalized (inpatient, out-patient, or emergency room visit) from the (10) years prior to your ovarian cancer diagnosis to the present:

[illegible]

<b>Name</b>	<b>Address</b>	<b>Admission Date(s)</b>	<b>Reason for Admission Approx. Years of Visits</b>
N/A	N/A		N/A



12. To the best of your recollection, identify each pharmacy that has regularly dispensed medication to you from the ten (10) years prior to your ovarian cancer diagnosis to the present:

Name of Pharmacy	Address of Pharmacy	Approx. Years You Used Pharmacy
		to
		to
		to
		to
		to
		to
		to
		to
		to
		to
		to
		to
		to

Name of Pharmacy	Address of Pharmacy	Approx. Years You Used Pharmacy
N/A	N/A	to
		to
		to
		to
		to
		to
		to
		to
		to
		to
		to
		to
		to
		to
		to
		to
		to

13. Has any health care provider told you the cause(s) of your ovarian cancer?

[REDACTED]

Healthcare Provider's Name	Approximate Date of Conversation	Substance of Conversation
[REDACTED]		

14. Have you had any communications with your health care providers, orally or in writing, about whether your condition is related to your use of Johnson’s Baby Powder and/or Shower to Shower?

[REDACTED]

Healthcare Provider’s Name	Approximate Date of Conversation
[REDACTED]	

**TALCUM POWDER PRODUCT USE**

16. Have you ever used Johnson's Baby Powder? Choose Yes/No: Yes

If yes, identify:

- a) Did you apply the product to your genital area? Choose Yes/No: Yes
- b) Approximate year of first use: 1970
- c) Approximate year of last use: 2015
- d) Frequency of use during these dates: Used daily

17. Have you ever used Johnson & Johnson Shower to Shower? Choose Yes/No: Yes

If yes, identify:

- a) Did you apply the product to your genital area? Choose Yes/No: Yes
- b) Approximate year of first use: 1982
- c) Approximate year of last use: 1983
- d) Frequency of use during these dates: Used daily

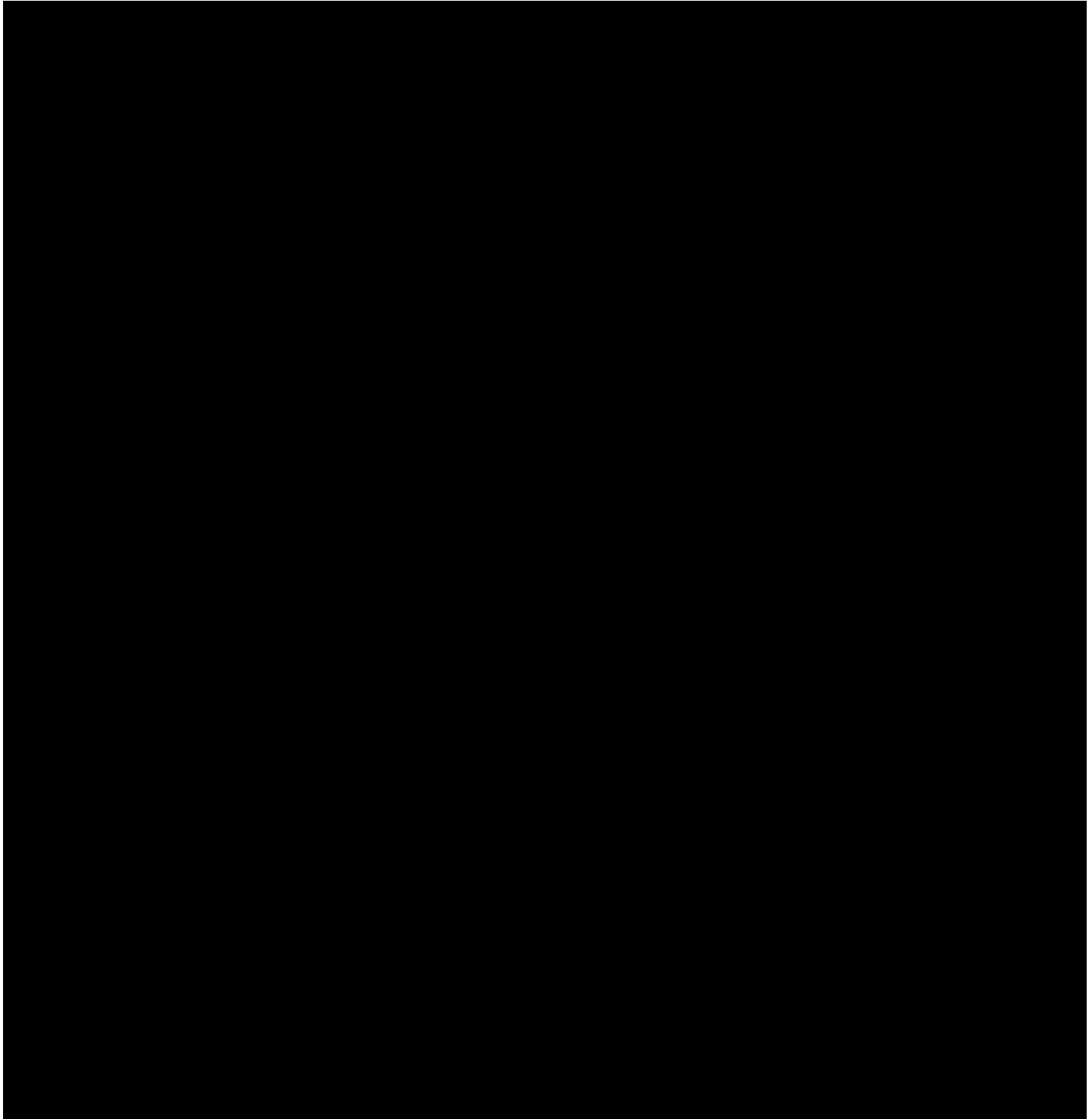
18. Have you ever used any other cosmetic powder product(s) in your genital area?

Choose Yes/No: No

If yes, identify:

- a) Name of product(s): N/A
- b) Approximate year of first use: \_\_\_\_\_
- c) Approximate year of last use: \_\_\_\_\_
- a) Name of product(s): N/A
- b) Approximate year of first use: \_\_\_\_\_
- c) Approximate year of last use: \_\_\_\_\_

**MEDICAL BACKGROUND OF BODY POWDER USER**





**24. Employment History:**

Are you currently employed? Choose Yes/No: <u>Yes</u>
---

If yes, please identify your current employer and position:
---

Town of Rochester, NH; Rochester Schools Special Education Counselor
--

**25. Education:**

Highest Educational Degree	Educational Institution
Post-Graduate	Lesley University (formerly Lesley College) and the

**DOCUMENT DEMANDS**

Documents in your possession, including writings on paper or in electronic form (if you have any of the following materials in your custody or possession, please indicate which documents you have and attach a copy of them to this Plaintiff Profile Form):

1. All documents relating to plaintiff's purchase(s) or acquisition(s) of Johnson's Baby Powder or Shower to Shower, including but not limited to, store receipts, credit card receipts, containers, labels, or other records of purchase or acquisition.
2. All medical records, reports, and/or documents from any hospital, physician, or other health care provider who treated plaintiff for ovarian cancer or any gynecologic disease, condition or symptom alleged in the Complaint and/or PPF.
3. If applicable, decedent-user's death certificate and copies of letters testamentary or letters of administration confirming standing of the named plaintiff.
4. A copy of all pathology reports related to plaintiff's/decedent's diagnosis or recurrence of ovarian cancer.
5. A copy of all reports reflecting any genetic testing undertaken on plaintiff/decedent.

**DECLARATION**

I declare under penalty of perjury that all of the information provided in connection with this Short Form Plaintiff Profile Form is true and correct to the best of my knowledge, information, and belief formed after due diligence and reasonable inquiry. I acknowledge that I have an obligation to supplement the above responses if I become aware of additional responsive information, or if I learn that they are in some material respects incomplete or incorrect.

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature of Plaintiff\_\_\_\_\_  
Print Name of Signing Plaintiff

# **EXHIBIT 38**

**PLAINTIFF PROFILE FORM**

This Plaintiff Profile Form (“PPF”) must be completed by the plaintiff or the representative of plaintiff’s decedent. In completing this PPF, you are under oath and must provide information that is true and complete to the best of your knowledge, information and belief after reasonable inquiry. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect.

In filling out this PPF, please use the following definitions: (1) “**health care provider**” means any hospital, clinic, medical center, physician’s office, infirmary, medical or diagnostic laboratory, or other facility that provides medical, dietary, psychiatric, or psychological care or advice, and any pharmacy, weight loss center, x-ray department, laboratory, physical therapist or physical therapy department, rehabilitation specialist, physician, psychiatrist, osteopath, homeopath, chiropractor, psychologist, nutritionist, dietician, or other persons or entities involved in the evaluation, diagnosis, care, and/or treatment of the plaintiff or plaintiff’s decedent; (2) “**document**” means any writing or record of every type that is in your possession, including but not limited to written documents, documents in electronic format, cassettes, videotapes, photographs, charts, computer discs or tapes, and x-rays, drawings, graphs, phone-records, non-identical copies, and other data compilations from which information can be obtained and translated, if necessary, by the respondent through electronic devices into reasonably usable form.

Information provided in this PPF will only be used for purposes related to this litigation and may be disclosed only as permitted by the protective order in this litigation. This PPF is completed pursuant to the Federal Rules of Civil Procedure governing discovery.

**1. CASE INFORMATION**

Name of Person Completing Form:	Tamara Newsome		
	First	M.I.	Last
If you are completing this PPF in a representative capacity (e.g., on behalf of the estate of a deceased person), please complete the following:			
Your Name:	N/A		
	First	M.I.	Last
Your relationship to individual you represent:	N/A		

**THE REST OF THIS PLAINTIFF PROFILE FORM REQUESTS INFORMATION ABOUT THE PERSON WHO USED JOHNSON'S BABY POWDER AND/OR SHOWER TO SHOWER AND WAS DIAGNOSED WITH OVARIAN CANCER**

**2. PERSONAL INFORMATION**

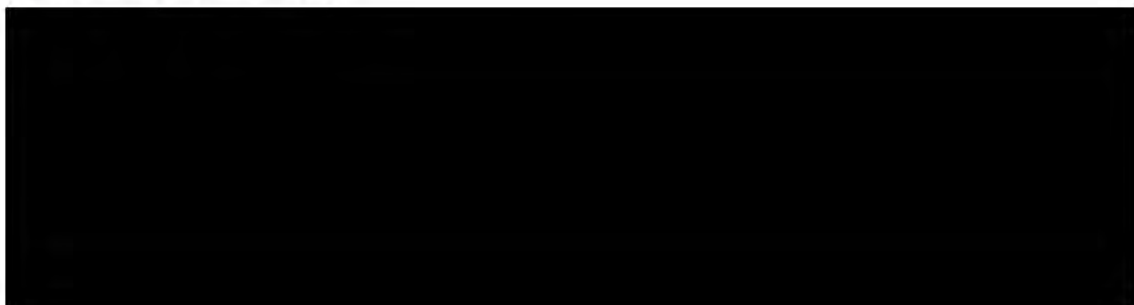
Name:	Tamara Newsome		
	First	M.I.	Last
Maiden/Other Names Used:	Francois		
Current or Last Known Address:	[REDACTED] Lanham MD 20706		
Date of Birth:	[REDACTED] 1961	Gender:	Male: <input type="checkbox"/> Female: <input checked="" type="checkbox"/>
Date of Death (If Applicable):	<input checked="" type="checkbox"/> N/A	Social Security Number: [REDACTED]	
Select Marriage Status:	Name of Spouse, if Married at time of filing Complaint:		
Married	Daniel Francois, Jr.		

3. **TALCUM POWDER-RELATED CLAIM**

- a. Have you been diagnosed with one of the following types of cancer? b. If yes, please provide the approximate date of initial diagnosis (if more than one, for each initial diagnosis). c. If you were diagnosed with ovarian cancer, fallopian tube or primary peritoneal cancer, please provide the type. d. If you were diagnosed with ovarian cancer, fallopian tube or primary peritoneal cancer, please provide the stage.

a. Type of Cancer	b. Date of Initial Diagnosis	c. Type of Ovarian, Fallopian tube, or Primary Peritoneal Cancer	d. Stage of Ovarian, Fallopian tube or Primary Peritoneal Cancer
Ovarian	Mar 23 2015	Endometrioid	Stage II

4. **MEDICAL HISTORY:**





c. Have you ever been diagnosed with any of the following?

Condition	Yes/No/Unknown	Name and Address of Diagnosing Provider	Approximate Date of Diagnosis (if applicable)
BRCA1 or BRCA2 mutation			
Endometriosis			
Adenomyosis			
Irregular vaginal bleeding			
Ovarian Cysts			
Polycystic ovaries and/or Polycystic Ovarian Syndrome (PCOS)			
Uterine fibroids			
Infertility			
Breast cancer			
Lynch Syndrome			

Condition	Yes/No/Unknown	Name and Address of Diagnosing Provider	Approximate Date of Diagnosis (if applicable)
Other cancer (please specify below):			
NONE			
Obesity/overweight			
Pelvic Inflammatory Disease (PID)			
Colon Polyps			

6. Other than those injuries that you believe were caused by your use of body powder, do you currently suffer from any chronic illnesses or disabilities?

**FAMILY MEDICAL HISTORY**

7. Limiting this question to blood relatives, to the best of your knowledge, please indicate whether your *parents, siblings, children, grandparents, aunts, uncles, or first cousins* have ever suffered from or been treated for any type of cancer (including but not limited to ovarian cancer or breast cancer):

Relative's Name	Relation to you	Type of cancer	Date of cancer

8. Limiting this question to blood relatives, to the best of your knowledge, please indicate whether your *parents, siblings, children, grandparents, aunts, uncles, or first cousins* have ever been diagnosed with any genetic mutations, including but not limited to BRCA1 or BRCA2 mutations?

**HEALTH CARE PROVIDERS AND PHARMACIES**

9. Limiting your answer to primary care, gynecology and oncology healthcare providers, identify each doctor or other health care provider who you have seen for medical care and treatment from the ten (10) years prior to your ovarian cancer diagnosis to the present. In particular, please use your best efforts to list all of the primary care providers during this period.

Doctor or Healthcare Provider's Name	Doctor or Healthcare Provider's Specialty	Address	Approximate Years of Visits
			to
			to
			to
			to

Doctor or Healthcare Provider's Name	Doctor or Healthcare Provider's Specialty	Address	Approximate Years of Visits
			to
			to
			to
			to
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			to

10. If any of your healthcare providers who you have seen in relation to treatment and care of **ovarian cancer or any other form of cancer** were not identified previously, please identify for each such provider:

[illegible]



11. Limiting your response to visits for issues related to cancer and to gynecologic issues other than pregnancy, identify each hospital, clinic, or health care facility where you were hospitalized (inpatient, out-patient, or emergency room visit) from the (10) years prior to your ovarian cancer diagnosis to the present:

Name	Address	Admission Date(s)	Reason for Admission Approx. Years of Visits

[illegible]

12. To the best of your recollection, identify each pharmacy that has regularly dispensed medication to you from the ten (10) years prior to your ovarian cancer diagnosis to the present:

Name of Pharmacy	Address of Pharmacy	Approx. Years You Used Pharmacy
		to
		to
		to
		to
		to
		to
		to
		to
		to
		to
		to

Name of Pharmacy	Address of Pharmacy	Approx. Years You Used Pharmacy
		to
		to
		to
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13. Has any health care provider told you the cause(s) of your ovarian cancer?



Healthcare Provider's Name	Approximate Date of Conversation	Substance of Conversation

14. Have you had any communications with your health care providers, orally or in writing, about whether your condition is related to your use of Johnson’s Baby Powder and/or Shower to Shower?

[REDACTED]

Healthcare Provider’s Name	Approximate Date of Conversation
[REDACTED]	



**TALCUM POWDER PRODUCT USE**

16. Have you ever used Johnson's Baby Powder? Choose Yes/No: Yes

If yes, identify:

- a) Did you apply the product to your genital area? Choose Yes/No: Yes
- b) Approximate year of first use: 1975
- c) Approximate year of last use: 2015
- d) Frequency of use during these dates: Every day

17. Have you ever used Johnson & Johnson Shower to Shower? Choose Yes/No: Yes

If yes, identify:

- a) Did you apply the product to your genital area? Choose Yes/No: Yes
- b) Approximate year of first use: 1975
- c) Approximate year of last use: 2015
- d) Frequency of use during these dates: Used when she could not find J&J baby

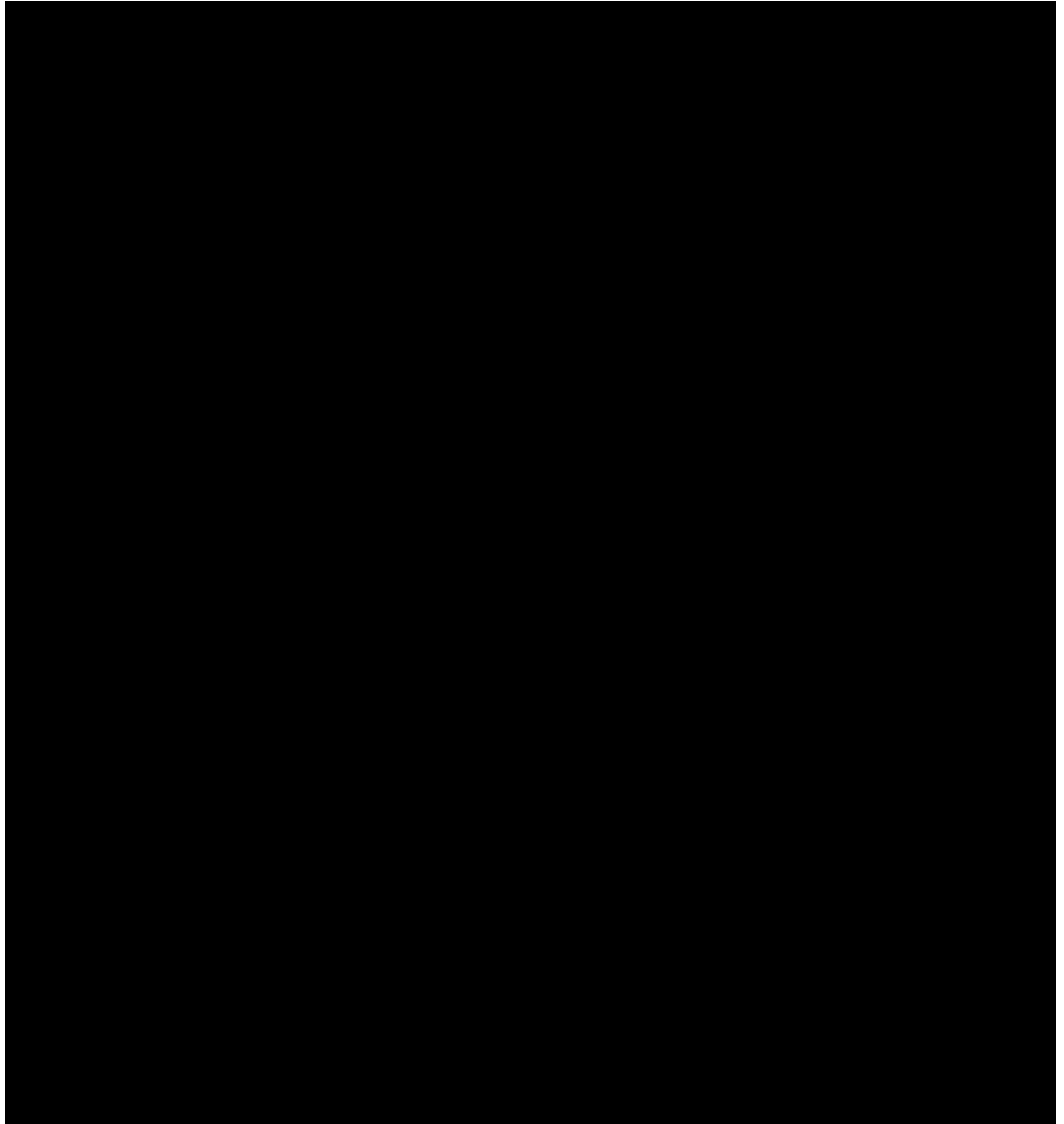
18. Have you ever used any other cosmetic powder product(s) in your genital area?

Choose Yes/No: Yes

If yes, identify:

- a) Name of product(s): Used unknown generic only 1 or 2 times total
- b) Approximate year of first use: \_\_\_\_\_
- c) Approximate year of last use: \_\_\_\_\_
  
- a) Name of product(s): N/A
- b) Approximate year of first use: \_\_\_\_\_
- c) Approximate year of last use: \_\_\_\_\_

**MEDICAL BACKGROUND OF BODY POWDER USER**



**24. Employment History:**

Are you currently employed? Choose Yes/No: <u>Yes</u>
---

If yes, please identify your current employer and position:
---

Capital Women's Care - Sonographer/Ultrasound
---

**25. Education:**

Highest Educational Degree	Educational Institution
High School Diploma	High Point College, Beltsville, MD

**DOCUMENT DEMANDS**

Documents in your possession, including writings on paper or in electronic form (if you have any of the following materials in your custody or possession, please indicate which documents you have and attach a copy of them to this Plaintiff Profile Form):

1. All documents relating to plaintiff's purchase(s) or acquisition(s) of Johnson's Baby Powder or Shower to Shower, including but not limited to, store receipts, credit card receipts, containers, labels, or other records of purchase or acquisition.
2. All medical records, reports, and/or documents from any hospital, physician, or other health care provider who treated plaintiff for ovarian cancer or any gynecologic disease, condition or symptom alleged in the Complaint and/or PPF.
3. If applicable, decedent-user's death certificate and copies of letters testamentary or letters of administration confirming standing of the named plaintiff.
4. A copy of all pathology reports related to plaintiff's/decedent's diagnosis or recurrence of ovarian cancer.
5. A copy of all reports reflecting any genetic testing undertaken on plaintiff/decedent.

**DECLARATION**

I declare under penalty of perjury that all of the information provided in connection with this Short Form Plaintiff Profile Form is true and correct to the best of my knowledge, information, and belief formed after due diligence and reasonable inquiry. I acknowledge that I have an obligation to supplement the above responses if I become aware of additional responsive information, or if I learn that they are in some material respects incomplete or incorrect.

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature of Plaintiff\_\_\_\_\_  
Print Name of Signing Plaintiff

# **EXHIBIT 39**

/jmt

Pathologist:  
SCOTT DRURY, M.D.  
Electronically Signed:  
<Sign Out Dr. Signature>  
04/14/2015 12:19

End of Report

**SURGICAL PATHOLOGY FINAL REPORT (#15021263, Final, 03/23/2015 12:59pm)**

Ordering Provider	ALBERT STEREN	Performing Lab	TRINITY HEALTH 27870 CABOT DRIVE NOVI MI 48377
Specimen/Accession ID	7675777068	Specimen Source	
Specimen Coll. Date	03/23/2015 12:59	Result Status	Final
Specimen Rec. Date		Report Status	
Specimen Reported Date	03/25/2015 09:26		

Report	Result	Ref. Range	Units	△	Status	Lab
SURGICAL PATHOLOGY					Final	
SEE BELOW DISCHARGED 03/24/2015 CC: Procedure Date: 03/23/2015 Accession Date: 03/23/2015 Case #: S15-2514  CLINICAL DATA: [REDACTED]  IOC/FROZEN: [REDACTED]  Received at 12:31, reported at 12:47.						



GROSS EXAMINATION:

DIAGNOSIS:

SYNOPTIC REPORT - Ovary

Pathologist:

Scott D. Newsome, MD.  
Electronically Signed:  
<Sign Out Dr. Signature>  
03/25/2015 09:22

End of Report

# **EXHIBIT 40**

